

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Informed Consent

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10951197]
2.	Birth Date:	(b) (6)/1982
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Sep/1/2020
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: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Anxiety]
	Start Date:	Jan/1/1996
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Degenerative disc disease]
	Start Date:	Jan/1/2013
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Depression]
	Start Date:	Jan/1/1993
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Epstein-Barr based on high IgG titers without acute infection]
	Start Date:	Jan/1/2019
	Ongoing:	YES

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Fibromyalgia]
	Start Date:	Jan/1/2020
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Iron deficient anemia]
	Start Date:	Jan/1/2010
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Irritable bowel syndrome]
	Start Date:	Jan/1/2012
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[pyelonephritis (both kidneys)]
	Start Date:	Apr/UNK/2017
	Ongoing:	NO End Date: Apr/UNK/2017

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ovarian cysts]
	Start Date:	Jan/1/2016
	Ongoing:	NO End Date: Jan/1/2016
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[laparoscopic cyst removal]
	Start Date:	Jan/UNK/2016
	Ongoing:	NO End Date: Jan/UNK/2016
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[spinal stenosis]
	Start Date:	Jan/1/2013
	Ongoing:	YES
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[seasonal allergies]
	Start Date:	Jan/UNK/1990
	Ongoing:	YES

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

1.m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Vitiligo]
	Start Date:	Jan/1/1994
	Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/1/2020
2.	Weight:	[84.6]
3.	Unit:	kg
4.	Height:	[176.0]
5.	Unit:	cm
6.	Body Mass Index:	[27.3]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[99.2]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

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

Lab Result

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Sep/1/2020
2.	Randomization Number:	[77334]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/1/2020
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	[BPY2XR]
5.b	Sample ID	[BPY2XS]
5.c	Sample ID	[BPY2XT]
5.d	Sample ID	[BPCT4C]

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/1/2020
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	[BP3BJ9]
-----	-----------	----------

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/1/2020 16:57
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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

[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: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/19/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

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

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.6]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Oct/19/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/19/2020
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	[BP1MMY]
5.b	Sample ID	[BP1MMZ]
5.c	Sample ID	[BP1MN0]
5.d	Sample ID	[BP1N70]

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	YES Date of First Delay: Oct/5/2020 Reason(s) for Temporary Delay of Vaccination RECENT SYSTEMIC CORTICOSTEROID TREATMENT
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/19/2020 16:09
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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/17/2020
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	[BPLJXF]
5.b	Sample ID	[BRDG34]
5.c	Sample ID	[BRDG35]
5.d	Sample ID	[BRDG36]

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1095) Tekton Research

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1095) Tekton Research

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1095) Tekton Research

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1095) Tekton Research

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1095) Tekton Research

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1095) Tekton Research

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Sep/21/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

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

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
on Sep/21/2020

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Not Complete

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Sep/21/2020
2.	Date of First Symptom Started:	Sep/19/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Oct/3/2020

Symptoms

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
on Sep/21/2020

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Not Complete

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Symptoms - Other

5.a	Symptoms - Other Text:	[Chills]
5.b	Symptoms - Other Text:	[Diarrhea]
5.e	Symptoms - Other Text:	[muscle pain]
5.d	Symptoms - Other Text:	[vomiting]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1. DELETED	Sep/21/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Sep/21/2020

Form Version: 06-Jul-2020 21:54

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

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

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Microbiology Specimen

1.	Actual Date of Collection:	Sep/21/2020	
2.	Specimen Type:	SWABBED MATERIAL	
3.	Specimen Collection Location:	NASOPHARYNX	
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	
5.	Device Type:	SARS COV 2 DIAGNOSTIC TEST	
6.	Trade Name:	Not Applicable	Comments
7.	Test Result:		
8.	Comments/Findings/Details:	[]	
9.	Trade Name Other, Specify:	[]	

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Sep/21/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	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	[CV17728]
-----	-----------	-----------

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
on Sep/21/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Sep/21/2020**Form Version:** 15-Sep-2020 21:53**Form Status:** Data Complete, Frozen, Verified**Site No:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951197**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[eCRF Audit Trail History](#)**Health Care Utilization**

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

Health Care Utilization Other

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

Health Care Utilization

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT
on Sep/21/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Respiratory Treatment

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

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS
on Sep/21/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS	Comments
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [upper respiratory infection] Date of Diagnosis: Sep/21/2020	Comments
3.	Toxicity Grade:	2	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

#	Category of Clinical Event	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Sep/21/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Illness Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Sep/21/2020

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Lab Chemistry Details

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

Lab Result

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

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Sep/21/2020

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Sep/21/2020

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

5.e	Sponsor ID:	Not Done _____ []	Comments
	Test:	Bilirubin_PX21	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Sep/21/2020

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

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

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

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology on Sep/21/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Laboratory Data Hematology

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

Lab Result

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Sep/21/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

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

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Sep/21/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Sep/21/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Sep/21/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Sep/21/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details			Form Instance
1.	Not Done	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		Not Applicable	Not Done	Not Done	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Sep/21/2020

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

1.	Date:	Not Done _____ //	Comments
----	-------	-------------------------	--------------------------

Vital Signs Details

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

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details		Form Instance
1.	Not Done	Record Identifier:	Oxygen Saturation	Repeating Pages
		Not Applicable	Not Done	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Sep/21/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

1.	Date:	Not Done _____ //	Comments
----	-------	-------------------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	Not Done _____ 1	
	SPO2 Pulse Oximetry %	Not Done _____ []	Comments

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS
on Sep/21/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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Oxygenation Parameters

1.	Date Time of Assessment:	Not Done _____ //	Comments
2.	Arterial Blood Gases PaO2 (mmHg):	Not Done _____ []	Comments
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Done _____ []	Comments

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
on Sep/21/2020

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Concomitant Medications

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING
on Sep/21/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Imaging

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Dec/29/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

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

COVID-19 Illness Visit

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

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
on Dec/29/2020

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Dec/29/2020
2.	Date of First Symptom Started:	Dec/27/2020
3.	Symptoms Ongoing?	NO
	Date of Last Symptom Resolved:	Dec/31/2020

Symptoms

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
on Dec/29/2020

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Symptoms - Other

5.a

Symptoms - Other Text:

[elevated temp-99.9 F]

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Dec/29/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Microbiology Specimen

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Dec/29/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Spoke with participant today and she reports she did not swab.PD written.]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
on Dec/29/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit Form: HEALTH CARE UTILIZATION
on Dec/29/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT
on Dec/29/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Respiratory Treatment

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** ILLNESS DETAILS
on Dec/29/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [Viral URI] Date of Diagnosis: Dec/29/2020
3.	Toxicity Grade:	2

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Dec/29/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Illness Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Dec/29/2020

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Lab Chemistry Details

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

Lab Result

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Dec/29/2020

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Dec/29/2020

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

5.e	Sponsor ID:	Not Done _____ []	Comments
	Test:	Bilirubin_PX21	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Dec/29/2020

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Dec/29/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Laboratory Data Hematology

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

Lab Result

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Dec/29/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Dec/29/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Dec/29/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Dec/29/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Dec/29/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details			Form Instance
1.	Not Done	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		Not Done	Not Done	Not Done	

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Dec/29/2020

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

1.	Date:	Not Done _____ //	Comments
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Vital Signs Details

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details		Form Instance
1.	Not Done	Record Identifier:	Oxygen Saturation	Repeating Pages
		Not Done	Not Done	

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Dec/29/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

1.	Date:	Not Done _____ //	Comments
----	-------	-------------------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	Not Done _____ 1	
	SPO2 Pulse Oximetry %	Not Done _____ []	Comments

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS
on Dec/29/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Oxygenation Parameters

1.	Date Time of Assessment:	Not Done _____ //	Comments
2.	Arterial Blood Gases PaO2 (mmHg):	Not Done _____ []	Comments
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Done _____ []	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
on Dec/29/2020

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Concomitant Medications

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

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Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** IMAGING
on Dec/29/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Imaging

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

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Jan/28/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Date of Visit

1.	Date of Visit	Jan/28/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
on Jan/28/2021

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Jan/28/2021
2.	Date of First Symptom Started:	Jan/25/2021
3.	Symptoms Ongoing?	NO
	Date of Last Symptom Resolved:	Jan/27/2021

Symptoms

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
on Jan/28/2021

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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Symptoms - Other

5.a

Symptoms - Other Text:

[elevated temp 99.9]

Header Text: c4591001

Visit: POT_COVID_ILL 3

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Jan/28/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Microbiology Specimen

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Jan/28/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Jan/28/2021
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	[CV00540]
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090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
on Jan/28/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 3 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Jan/28/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete, Frozen**Site No:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951197**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[eCRF Audit Trail History](#)**Health Care Utilization**

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

Health Care Utilization Other

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

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO
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Header Text: c4591001

Visit: POT_COVID_ILL 3

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

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Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT
on Jan/28/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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Respiratory Treatment

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** ILLNESS DETAILS
on Jan/28/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [viral upper respiratory infection] Date of Diagnosis: Jan/28/2021
3.	Toxicity Grade:	1

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Header Text: c4591001

Visit: POT_COVID_ILL 3

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

#	Category of Clinical Event	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Jan/28/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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Illness Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 3

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Jan/28/2021

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Lab Chemistry Details

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

Lab Result

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Jan/28/2021

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.b	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

5.c	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____ []	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Jan/28/2021

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

5.e	Sponsor ID:	Not Applicable _____	Comments
		[]	
	Test:	Bilirubin_PX21	
	Result:	Not Applicable _____	Comments
		[]	
Not Done:	Not Applicable _____	Comments	
LNMT	Not Applicable _____	Comments	
	Low [] High [] Unit		

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Jan/28/2021

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

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Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Jan/28/2021

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Laboratory Data Hematology

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

Lab Result

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Jan/28/2021

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.b	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Hematocrit_PX2	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

5.c	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Erythrocytes_PX3	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Jan/28/2021

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Jan/28/2021

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.f	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Neutrophils_PX608	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

5.g	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Eosinophils_PX609	
	Result:	Not Applicable _____ []	Comments
	Not Done:	Not Applicable _____	Comments
	LNMT	Not Applicable _____ Low [] High [] Unit	Comments

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Jan/28/2021

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.h	Sponsor ID:	Not Applicable _____	Comments
		[]	
	Test:	Monocytes_PX612	
	Result:	Not Applicable _____	Comments
		[]	
Not Done:	Not Applicable _____	Comments	
LNMT	Not Applicable _____	Comments	
	Low [] High [] Unit		

5.i	Sponsor ID:	Not Applicable _____	Comments
		[]	
	Test:	Basophils_PX610	
	Result:	Not Applicable _____	Comments
		[]	
Not Done:	Not Applicable _____	Comments	
LNMT	Not Applicable _____	Comments	
	Low [] High [] Unit		

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Jan/28/2021

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details			Form Instance
1.	Not Applicable	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		Not Applicable	Not Applicable	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Jan/28/2021

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

1.	Date:	Not Applicable _____ //	Comments
----	-------	-------------------------------	--------------------------

Vital Signs Details

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details		Form Instance
1.	Not Applicable	Record Identifier:	Oxygen Saturation	Repeating Pages
		Not Applicable	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Jan/28/2021

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

1.	Date:	Not Applicable _____ //	Comments
----	-------	-------------------------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	Not Applicable _____ 1	
	SPO2 Pulse Oximetry %	Not Applicable _____ []	Comments

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS
on Jan/28/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Oxygenation Parameters

1.	Date Time of Assessment:	Not Applicable _____ //	Comments
2.	Arterial Blood Gases PaO2 (mmHg):	Not Applicable _____ []	Comments
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Applicable _____ []	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 3

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
on Jan/28/2021

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Concomitant Medications

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** IMAGING
on Jan/28/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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[eCRF Audit Trail History](#)

Imaging

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Oct/19/2020

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/19/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Oct/19/2020

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/19/2020
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	[BP1MMY]
5.b	Sample ID	[BP1MMZ]
5.c	Sample ID	[BP1MN0]
5.d	Sample ID	[BPLJSP]
5.e	Sample ID	[BPLJSR]

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 2 - Unscheduled
Visit on Feb/26/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

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

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_C1
----	-------------------------	----------

Header Text: c4591001

Visit: POT_COVID_CONVA 2 - Unscheduled
Visit on Feb/26/2021

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/26/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRBTJ5]
5.b	Sample ID	[BRBTJ6]
5.c	Sample ID	[BRBTJ7]

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Sep/21/2020

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Sep/21/2020

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Unplanned Assessments

1.	Assessments	CONTACT OUTCOME
----	-------------	-----------------

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Sep/21/2020

Form: CONTACT OUTCOME - UNPLANNED

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Sep/21/2020 Contact Outcome: VISIT NOT ARRANGED, UNABLE TO ATTEND
3.	Comments:	[Subject reports productive cough, sore throat and myalgia for 3 days. Denies fever or other symptoms. Subject spoke with co-PI. Subject will do nasal swab at home as instructed.]

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on
Nov/02/2020

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on
Nov/02/2020

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Unplanned Assessments

1.	Assessments	CONTACT OUTCOME
----	-------------	-----------------

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on
Nov/02/2020

Form: CONTACT OUTCOME - UNPLANNED

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Nov/2/2020 Contact Outcome: VISIT ARRANGED
3.	Comments:	[]

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on
Nov/02/2020

Form: VITAL SIGNS - TEMP

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Nov/2/2020
----	-------	------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.1]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on Nov/02/2020

Form Version: 10-Oct-2020 15:57

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Unplanned Assessment Of Local Reaction

1.	Date of Assessment:	Nov/2/2020
2.	Injection Site Location	DELTOID MUSCLE
3.	Injection Site Body Side:	LEFT

Reaction

4.a	Reaction:	REDNESS
	Reaction Present:	NO
4.b	Reaction:	SWELLING
	Reaction Present:	NO

Symptom

5.a	Symptom:	PAIN AT INJECTION SITE
	Symptom Present:	NO
5.b	Symptom:	FATIGUE/TIREDNESS
	Symptom Present:	NO
5.c	Symptom:	HEADACHE
	Symptom Present:	NO
5.d	Symptom:	VOMITING
	Symptom Present:	NO
5.e	Symptom:	DIARRHEA
	Symptom Present:	NO
5.f	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Symptom Present:	NO
5.g	Symptom:	NEW OR WORSENERED JOINT PAIN
	Symptom Present:	NO

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on
Nov/02/2020

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.h	Symptom:	CHILLS
	Symptom Present:	NO

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Nov/17/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1095) Tekton Research

Subject Initials: ---

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

Disposition - Follow-Up

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1. DELETED	ADVERSE EVENT	1	upper respiratory infection	Sep/19/2020 UNK:UNK	NO End Date Time: Oct/3/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Fixed drug eruption on feet bilaterally	Oct/26/2020 UNK:UNK	YES	Repeating Pages
3.	ADVERSE EVENT	3	exacerbation of Degenerative Disc Disease	Jan/14/2021 UNK:UNK	NO End Date Time: Jan/15/2021 UNK:UNK	Repeating Pages

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

Site Name: (1095) Tekton Research

Subject Initials: ---

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

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[+]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[upper respiratory infection]
4.	Start Date Time:	Sep/19/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/3/2020 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: [viral infection]

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

Site Name: (1095) Tekton Research

Subject Initials: ---

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

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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1095) Tekton Research

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fixed drug eruption on feet bilaterally]
4.	Start Date Time:	Oct/26/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
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:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1095) Tekton Research

Subject Initials: ---

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

13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1095) Tekton Research

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[exacerbation of Degenerative Disc Disease]
4.	Start Date Time:	Jan/14/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/15/2021 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event 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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1095) Tekton Research

Subject Initials: ---

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

9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [DEGENERATIVE DISC DISEASE]
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	[2021218683]

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1095) Tekton Research

Subject Initials: ---

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

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Medication Error

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						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: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Concomitant Medications

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1095) Tekton Research

Subject Initials: ---

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

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Concomitant Medications

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1095) Tekton Research

Subject Initials: ---

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

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Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

#	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: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1095) Tekton Research

Subject Initials: ---

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

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16

Form Status: Not Started

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Lab Urinalysis

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

Lab Result

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Vaccination

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (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: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Contact Outcome

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Contact Outcome

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Informed Consent - Asymptomatic Surveillance

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

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: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/23/2021
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: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per other protocol allowance(s) 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: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/23/2021
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: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1095) Tekton Research

Subject Initials: ---

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

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1095) Tekton Research

Subject Initials: ---

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

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Nov/17/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

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Item	Date	User	Comment
Form	Sep-01-2020 16:41:50 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	N/A
Form	Sep-01-2020 16:41:37 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Sep/21/2020

Form Version: 06-Jul-2020 21:54

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

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

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Item	Date	User	Comment
6	Oct-06-2020 08:41:17 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	entered information incorrectly. COVID microbiology specimen not collected <hr/> Not Applicable
6	Sep-30-2020 14:18:44 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	entered information incorrectly. COVID microbiology specimen not collected
6	Sep-30-2020 12:59:00 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	entered information incorrectly. <hr/> Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Nov-03-2020 08:23:54 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
Form	Sep-30-2020 13:48:53 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
Form	Sep-29-2020 14:59:47 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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1	Sep-30-2020 13:48:53 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
1	Sep-29-2020 14:59:47 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

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Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB -
Comments

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Site No: 1095

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Item	Date	User	Comment
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2	Sep-30-2020 13:48:53 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
2	Sep-29-2020 14:59:47 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
3	Nov-03-2020 08:23:54 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
3	Sep-30-2020 13:48:53 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
3	Sep-29-2020 14:59:47 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
4	Nov-03-2020 08:23:54 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
4	Sep-30-2020 13:48:53 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
4	Sep-29-2020 14:59:47 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
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Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

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Item	Date	User	Comment
Form	Oct-21-2020 09:16:36 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
Form	Oct-19-2020 18:07:43 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
Form	Sep-30-2020 13:49:23 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
Form	Sep-29-2020 15:00:07 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
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Site No: 1095

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Item	Date	User	Comment
1	Oct-21-2020 09:16:36 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
1	Oct-19-2020 18:07:43 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
1	Sep-30-2020 13:49:23 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
1	Sep-29-2020 15:00:07 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
2	Oct-21-2020 09:16:36 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
2	Oct-19-2020 18:07:43 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
2	Sep-30-2020 13:49:23 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
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Item	Date	User	Comment
3	Oct-21-2020 09:16:36 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
3	Oct-19-2020 18:07:43 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
3	Sep-30-2020 13:49:23 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
3	Sep-29-2020 15:00:07 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
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Form Status: Data Complete, Frozen

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Item	Date	User	Comment
4	Oct-21-2020 09:16:36 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
4	Oct-19-2020 18:07:43 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
4	Sep-30-2020 13:49:23 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
4	Sep-29-2020 15:00:07 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
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Site No: 1095

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Item	Date	User	Comment
5	Oct-21-2020 09:16:36 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
5	Oct-19-2020 18:07:43 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
5	Sep-30-2020 13:49:23 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
5	Sep-29-2020 15:00:07 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
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Site No: 1095

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Item	Date	User	Comment
6	Oct-21-2020 09:16:36 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
6	Oct-19-2020 18:07:43 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
6	Sep-30-2020 13:49:23 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
6	Sep-29-2020 15:00:07 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - Comments
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Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

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Item	Date	User	Comment
Form	Sep-30-2020 14:15:27 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
Form	Sep-29-2020 15:00:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 06-Jul-2020 21:52

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: ILLNESS DETAILS - Comments

Form Status: Data Complete, Frozen, Verified

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Item	Date	User	Comment
1	Sep-30-2020 14:15:27 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
1	Sep-29-2020 15:00:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

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Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: ILLNESS DETAILS - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1095) Tekton Research

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Item	Date	User	Comment
2	Sep-30-2020 14:15:27 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
2	Sep-29-2020 15:00:21 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
on Sep/21/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

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Item	Date	User	Comment
Form	Oct-21-2020 09:16:47 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
Form	Oct-21-2020 08:44:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
Form	Oct-21-2020 08:25:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
Form	Oct-19-2020 18:07:59 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
Form	Sep-29-2020 15:00:39 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
on Sep/21/2020

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Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

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Item	Date	User	Comment
1	Oct-21-2020 09:16:47 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
1	Oct-21-2020 08:44:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
1	Oct-21-2020 08:25:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
1	Oct-19-2020 18:07:59 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
1	Sep-29-2020 15:00:39 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
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Item	Date	User	Comment
2	Oct-21-2020 09:16:47 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
2	Oct-21-2020 08:44:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
2	Oct-21-2020 08:25:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
2	Oct-19-2020 18:07:59 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
2	Sep-29-2020 15:00:39 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

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Item	Date	User	Comment
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3	Oct-21-2020 08:44:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
3	Oct-21-2020 08:25:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
3	Oct-19-2020 18:07:59 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
3	Sep-29-2020 15:00:39 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
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Form Status: Data Complete, Frozen

Site No: 1095

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Item	Date	User	Comment
4	Oct-21-2020 09:16:47 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
4	Oct-21-2020 08:44:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
4	Oct-21-2020 08:25:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
4	Oct-19-2020 18:07:59 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
4	Sep-29-2020 15:00:39 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
Form	Oct-21-2020 09:16:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
Form	Oct-19-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
Form	Sep-30-2020 13:50:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
Form	Sep-29-2020 15:01:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

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Subject No: 10951197

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Item	Date	User	Comment
1	Oct-21-2020 09:16:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
1	Oct-19-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
1	Sep-30-2020 13:50:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
1	Sep-29-2020 15:01:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
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2	Oct-19-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
2	Sep-30-2020 13:50:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
2	Sep-29-2020 15:01:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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3	Oct-19-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
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3	Sep-29-2020 15:01:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

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Item	Date	User	Comment
4	Oct-21-2020 09:16:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
4	Oct-19-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
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Item	Date	User	Comment
5.a	Oct-21-2020 09:16:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
5.a	Oct-19-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
5.a	Sep-30-2020 13:50:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
5.a	Sep-29-2020 15:01:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
5.g	Oct-21-2020 09:16:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
5.g	Oct-19-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
5.g	Sep-30-2020 13:50:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
5.g	Sep-29-2020 15:01:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

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Item	Date	User	Comment
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5.g	Oct-19-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
5.g	Sep-30-2020 13:50:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
5.g	Sep-29-2020 15:01:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

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5.g	Oct-19-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
5.g	Sep-30-2020 13:50:13 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
5.g	Sep-29-2020 15:01:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

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Form	Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
Form	Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
Form	Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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1	Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
1	Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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2	Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
2	Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
2	Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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3	Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
3	Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
3	Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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4	Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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5.b	Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
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5.c	Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
5.c	Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
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5.d	Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
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5.d	Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
5.d	Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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5.e	Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

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Form	Oct-21-2020 09:17:23 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
Form	Oct-19-2020 18:08:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
Form	Sep-30-2020 13:50:43 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
Form	Sep-29-2020 15:02:22 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Comments
on Sep/21/2020

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen

Site No: 1095

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Subject No: 10951197

Subject Initials: ---

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1	Oct-19-2020 18:08:40 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
1	Sep-30-2020 13:50:43 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
1	Sep-29-2020 15:02:22 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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2.a	Sep-29-2020 15:02:22 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

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2.a	Sep-30-2020 13:50:43 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
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2.a	Sep-30-2020 13:50:43 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
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Form	Oct-19-2020 18:08:50 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
Form	Sep-30-2020 13:51:01 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
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Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments on Sep/21/2020

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1	Sep-29-2020 15:02:39 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments
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2.a	Sep-30-2020 13:51:01 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
2.a	Sep-29-2020 15:02:39 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
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Site No: 1095

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Item	Date	User	Comment
Form	Oct-21-2020 09:17:46 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
Form	Oct-19-2020 18:09:08 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
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Form	Sep-29-2020 15:02:49 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
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Form Status: Data Complete, Frozen

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Item	Date	User	Comment
1	Oct-21-2020 09:17:46 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
1	Oct-19-2020 18:09:08 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
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1	Sep-29-2020 15:02:49 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
3	Oct-21-2020 09:17:46 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
3	Oct-19-2020 18:09:08 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
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3	Sep-29-2020 15:02:49 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Form Status: Data Complete, Frozen

Site No: 1095

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Item	Date	User	Comment
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Form	Oct-19-2020 18:09:19 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
Form	Sep-30-2020 13:51:31 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
Form	Sep-29-2020 15:03:00 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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4	Sep-29-2020 15:03:00 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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5	Oct-21-2020 09:18:02 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
5	Oct-19-2020 18:09:19 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
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5	Sep-29-2020 15:03:00 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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6	Oct-21-2020 09:18:02 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
6	Oct-19-2020 18:09:19 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
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Form	Oct-19-2020 18:09:31 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
Form	Sep-30-2020 13:51:43 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done
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Header Text: c4591001

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Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1095

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
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Header Text: c4591001

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Header Text: c4591001

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Form Status: Data Complete, Frozen

Site No: 1095

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Header Text: c4591001

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Form Status: Data Complete, Frozen

Site No: 1095

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Generated By: (b) (4)

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Item	Date	User	Comment
3	Dec-29-2020 11:22:19 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** IMAGING - Comments
on Dec/29/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
4	Dec-29-2020 11:22:19 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Jan/28/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
Form	Feb-02-2021 11:17:52 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
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Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1095

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Item	Date	User	Comment
1	Feb-02-2021 11:17:52 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
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Form Status: Data Complete, Frozen

Site No: 1095

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Item	Date	User	Comment
2	Feb-02-2021 11:17:52 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
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Item	Date	User	Comment
5	Feb-02-2021 11:17:52 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
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Item	Date	User	Comment
6	Feb-02-2021 11:17:52 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

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Item	Date	User	Comment
7	Feb-02-2021 11:17:52 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

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Form Status: Data Complete, Frozen

Site No: 1095

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Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

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9	Feb-02-2021 11:17:52 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

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Form Status: Data Complete, Frozen

Site No: 1095

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Item	Date	User	Comment
Form	Jan-28-2021 14:51:31 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
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Item	Date	User	Comment
1	Jan-28-2021 14:51:31 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
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Item	Date	User	Comment
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Header Text: c4591001

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Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
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Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1095

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Item	Date	User	Comment
Form	Jan-28-2021 14:52:46 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
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Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1095

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Item	Date	User	Comment
1	Jan-28-2021 14:52:46 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

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Item	Date	User	Comment
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Header Text: c4591001

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Item	Date	User	Comment
4	Jan-28-2021 14:52:46 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit on Jan/28/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
Form	Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

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Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

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Item	Date	User	Comment
1	Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit on Jan/28/2021

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5.a	Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Visit: POT_COVID_ILL 3 - Unscheduled Visit on Jan/28/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
6	Jan-28-2021 14:55:01 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** IMAGING - Comments
on Jan/28/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Jan-28-2021 14:55:35 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** IMAGING - Comments
on Jan/28/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
1	Jan-28-2021 14:55:35 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** IMAGING - Comments
on Jan/28/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2	Jan-28-2021 14:55:35 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** IMAGING - Comments
on Jan/28/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
3	Jan-28-2021 14:55:35 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** IMAGING - Comments
on Jan/28/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
4	Jan-28-2021 14:55:35 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Jan-28-2021 14:49:23 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

Paul Pickrell	Approved	Jan-25-2021 21:22:55 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
---------------	----------	---	------	--------

Affidavit:

By my dated signature below, I, PaulPickrell, 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-18-2020 10:17:15 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Paul Pickrell	Approved	Nov-17-2020 19:55:35 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, PaulPickrell, 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.

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

(b) (6)	N/A	Nov-17-2020 16:43:36 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Paul Pickrell	Approved	Nov-10-2020 21:23:13 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, PaulPickrell, 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.

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-01-2020 16:40:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 16:40:05 (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: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

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I. Consent Was:

Date	Location	User	Value	Reason
Sep-01-2020 16:40:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Sep/1/2020	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

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1. Subject ID

Date	Location	User	Value	Reason
Sep-01-2020 16:39:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10951197	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-01-2020 16:36:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1982	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-01-2020 16:40:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-01-2020 16:40:49 (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-01-2020 16:40:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Sep-01-2020 16:41:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-01-2020 16:42:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-01-2020 16:42:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-01-2020 16:42:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

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I.a

Date	Location	User	Value	Reason
Sep-01-2020 17:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term Anxiety : Start Date: Jan/1/199 6 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:31:48 (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-01-2020 17:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Anxiety	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 17:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/1/1996	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 17:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.b

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

Date	Location	User	Value	Reason
Sep-01-2020 17:32:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 2 ber: Medical History Term: Degenerative disc disease Start Date: Jan/1/2013 Ongoing: YES	Initial Entry

1.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:32:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 17:32:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Degenerative disc disease	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 17:32:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/1/2013	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 17:32:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Sep-01-2020 17:33:04 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

Time (US & Canada)			Medical History Term: Depression	
			Start Date: Jan/1/1993	
			Ongoing: YES	
Sep-01-2020 17:32:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: Medical History Term: Start Date: Jan/1/1993 Ongoing: YES	Initial Entry

1.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:33:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 17:33:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Depression	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 17:32:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/1/1993	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 17:32:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.d

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

Date	Location	User	Value	Reason
Sep-02-2020 11:43:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 4 Medical History Term: Epstein-Barr based on high IgG titers without acute infection Start Date: Jan/1/2019 Ongoing: YES	New Information
Sep-01-2020 17:33:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: Epstein-Barr Start Date: Jan/1/2019 Ongoing: YES	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

I.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:33:43 (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-02-2020 15:11:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: C losed	Discrepancy has been closed.
Sep-02-2020 11:43:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: A nswered	New Information
Sep-02-2020 11:43:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entr y: Epstein-Ba rr based on high IgG ti ters withou t acute infe ction	New Information
Sep-02-2020 02:23:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: O pened	Clarify EPSTEIN-BARR as follows...Organism only reported. Please clarify if reporting EPSTEIN-BARR VIRUS TEST or EPSTEIN-BARR VIRUS TEST POSITIVE or EPSTEIN-BARR VIRUS INFECTION or other and update

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

				the verbatim term accordingly. Thank you.
Sep-01-2020 17:33:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Epstein-Barr	Initial Entry

1.d Start Date

Date	Location	User	Value	Reason
Sep-01-2020 17:33:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/1/2019	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 17:33:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.e

Date	Location	User	Value	Reason
Sep-01-2020 17:34:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: Fibromyalgia Start Date: Jan/1/2020 Ongoing: YES	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

I.e Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:34:31 (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-01-2020 17:34:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Fibromyalgia	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 17:34:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/1/2020	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 17:34:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Sep-01-2020 17:35:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Term: Iron deficient anemia Start Date: Jan/1/2010 Ongoing: YES	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

1.f Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:35:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

1.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-01-2020 17:35:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Iron deficient anemia	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 17:35:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/1/2010	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 17:35:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.g

Date	Location	User	Value	Reason
Sep-01-2020 17:35:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 7 Medical History Term: Irritable bowel syndrome Start Date: Jan/1/2012 Ongoing: YES	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

I.g Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:35:30 (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-01-2020 17:35:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Irritable bowel syndrome	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 17:35:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/1/2012	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 17:35:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.h

Date	Location	User	Value	Reason
Sep-01-2020 17:44:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 8 Medical History Term: pyelonephritis (both kidneys) Start Date: Apr/UNK/2017 Ongoing: NO End Date: Apr/UNK/2017	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

1.h Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:44:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 17:44:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: pyelonephritis (both kidneys)	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 17:44:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Apr/UNK/2017	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 17:44:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Apr/UNK/2017	Initial Entry

1.i

Date	Location	User	Value	Reason
Sep-01-2020 17:45:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 9 Medical History Term: ovarian cysts Start Date: Jan/1/2016 Ongoing: NO End Date: Jan/1/2016	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

1.i Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:45:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 17:45:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ovarian cysts	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 17:45:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/1/2016	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

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1.i Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 17:45:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Jan/1/2016	Initial Entry

1.j

Date	Location	User	Value	Reason
Sep-01-2020 17:46:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 10 Medical History Term: laparoscopic cyst removal Start Date: Jan/UNK/2016 Ongoing: NO End Date: Jan/UNK/2016	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

1.j Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:46:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

1.j Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-01-2020 17:46:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: laparoscopic cyst removal	Initial Entry

1.j Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 17:46:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/UNK/2016	Initial Entry

1.j Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 17:46:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Jan/UNK/2016	Initial Entry

1.k

Date	Location	User	Value	Reason
Sep-01-2020 17:47:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 11 Medical History Term: spinal stenosis Start Date: Jan/1/2013 Ongoing: YES	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

1.k Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:47:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

1.k Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-01-2020 17:47:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: spinal stenosis	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 17:47:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/1/2013	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 17:47:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.l

Date	Location	User	Value	Reason
Sep-01-2020 17:48:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 12 Medical History Term: seasonal allergies Start Date: Jan/UNK/1990 Ongoing: YES	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

1.1 Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:48:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 17:48:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: seasonal allergies	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 17:48:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/UNK/1990	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 17:48:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.m

Date	Location	User	Value	Reason
Sep-01-2020 17:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 13 Medical History Term Vitiligo : Start Date: Jan/1/1994 Ongoing: YES	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

I.m Line/MH Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 13	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 17:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Vitiligo	Initial Entry

I.m Start Date:

Date	Location	User	Value	Reason
Sep-01-2020 17:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/1/1994	Initial Entry

I.m Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 17:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Sep-01-2020 16:45:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-01-2020 16:45:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 84.6	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-01-2020 16:45:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-01-2020 16:45:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 176.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-01-2020 16:45:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-01-2020 16:45:53 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 27.3	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

Time (US & Canada)

7.a

Date	Location	User	Value	Reason
Sep-01-2020 16:45:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier 1 : Temperature: 99.2 Temperature Unit: Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-01-2020 16:45:53 (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-01-2020 16:45:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 99.2	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-01-2020 16:45:53 (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-01-2020 16:45:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-01-2020 16:46:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-01-2020 16:46:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-01-2020 16:46:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-01-2020 16:46:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-01-2020 16:46:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-01-2020 16:46:15	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-06:00) Central Time (US & Canada)	(autocalc)	Sponsor-Defined Identifier: Test:: Choriogonadotropin in Beta_PX113 Result:: NEGATIVE Not Done::
--	------------	---

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-01-2020 16:46:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-01-2020 16:46:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX1 13	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-01-2020 16:46:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

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1. Randomization Date :

Date	Location	User	Value	Reason
Sep-01-2020 17:50:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-01-2020 17:50:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 77334	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (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: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Sep-01-2020 16:46:35 (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-01-2020 16:46:35 (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-01-2020 18:17:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-01-2020 16:46:35 (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-01-2020 16:46:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/1/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-01-2020 18:17:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPY2XR	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (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: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 18:17:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPY2XR	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-01-2020 18:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPY2XS	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 18:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPY2XS	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-01-2020 18:17:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPY2XT	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 18:17:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPY2XT	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-01-2020 18:17:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPCT4C	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (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: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 18:17:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPCT4C	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Sep-01-2020 16:46:47 (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-01-2020 16:46:47 (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-01-2020 18:17:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-01-2020 16:46:47 (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-01-2020 16:46:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/1/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-01-2020 18:17:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP3BJ9	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (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: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 18:17:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP3BJ9	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-01-2020 17:51:13 (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-01-2020 17:51:13 (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-01-2020 17:51:13 (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-01-2020 17:51:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/1/2020 16:57	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-01-2020 17:51:13 (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-01-2020 17:51:13 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

Time (US & Canada)

(b) (4), (b) (6)

7. Route:

Date	Location	User	Value	Reason
Sep-01-2020 17:51:13 (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-01-2020 17:51:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 17:51:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-01-2020 16:47:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E-D IARY NOT COLLECTED FO R THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-24-2020 05:44:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Clos ed	Response satisfies query
Oct-23-2020 13:43:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Ans wered	visits were combined-same date
Oct-23-2020 02:19:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Ope ned	DMW5087045;The Date of Visit at Visit V2_VAX2_L is the same as the other Date of Visit at Visit COVID_A1. Please review for duplication and update as appropriate.
Oct-21-2020 01:38:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Clos ed	TDV updated as YES
Oct-20-2020 10:03:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Ans wered	This has been updated
Oct-20-2020 01:02:26 (UTC-06:00)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 2: Ope ned	PDQ: Date of visit at V2_VAX2_L is out of window for 25

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

Central Time (US & Canada)				days from VI_DAY1_VAX1_L Dose Date. Please verify and update. Else, confirm in query response appropriately. (b) (4)
Oct-19-2020 16:13:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19 /2020	Initial Entry
Sep-27-2020 02:46:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-25-2020 07:23:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This visit will occur out of window
Sep-25-2020 05:49:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly review and complete 'Date of Visit, Nasal Swab, Pregnancy Test, Vaccination, Vital Signs' forms at this visit. Thank you.

2. Erroneous Visit

Date	Location	User	Value	Reason
Oct-14-2020 10:50:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Changed Information
Oct-14-2020 10:50:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ERRONEOUS VISIT	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Oct-19-2020 16:13:38 (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 16:13:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: 1 : Temperature: 97.6 Temperature Unit F : Temperature Location: ORAL CAV ITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-19-2020 16:13:38 (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
Oct-19-2020 16:13:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.6	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-19-2020 16:13:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

2.a Temperature Location:

Date	Location	User	Value	Reason
Oct-19-2020 16:13:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Oct-19-2020 16:13:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Oct-19-2020 16:13:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-19-2020 16:13:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Oct-19-2020 16:13:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Oct-19-2020 16:13:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Oct-19-2020 16:13:46	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-06:00) Central Time (US & Canada)	(autocalc)	Sponsor-Defined Identifier: 113	
		Test:: Choriogonadotropin Beta_PX113	
		Result:: NEGATIVE	
		Not Done::	

6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-19-2020 16:13:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-19-2020 16:13:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Oct-19-2020 16:13:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
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Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Oct-19-2020 16:13:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-19-2020 16:13:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-20-2020 17:51:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Deleted	Close Auto Query
Oct-20-2020 17:51:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-20-2020 17:50:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Oct-20-2020 17:50:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	There are more than 1 barcode present for sample collection. Please review and correct as appropriate.
Oct-20-2020 17:50:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (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:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951197**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39

Oct-20-2020 16:53:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	There are more than 1 barcode present for sample collection. Please review and correct as appropriate.
Oct-20-2020 16:53:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-20-2020 09:46:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-19-2020 16:13:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-19-2020 16:13:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/19/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-20-2020 17:50:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP1IMMY	Transcription Error (DELETED)
Oct-20-2020 16:53:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP1IMMY	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 17:50:32	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
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Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	BP1IMMY	(DELETED)
Oct-20-2020 16:53:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP1IMMY	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-20-2020 17:50:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP1IMMZ	Transcription Error (DELETED)
Oct-20-2020 16:53:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP1IMMZ	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 17:50:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP1IMMZ	Transcription Error (DELETED)
Oct-20-2020 16:53:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP1IMMZ	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-20-2020 17:51:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP1MNO	Transcription Error (DELETED)
Oct-20-2020 16:53:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP1MNO	Initial Entry

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Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
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Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 17:51:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP1MN0	Transcription Error (DELETED)
Oct-20-2020 16:53:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP1MN0	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-20-2020 17:51:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP1N70	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 17:51:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP1N70	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-20-2020 10:02:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of First Delay: Oct/5/2020 Reason(s) for Temporary Dela y of Vaccination RECENT SYSTEMIC CORT ICOSTEROID TREATMEN T	Transcription Error
Oct-19-2020 16:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Oct-19-2020 16:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-19-2020 16:17:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Changed Information
Oct-19-2020 16:14:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	'Was there a temporary delay of vaccination?' is marked as Yes and 'Reason(s) for Temporary Delay of Vaccination' is not entered. Please review and update as appropriate.
Oct-19-2020 16:14:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Was there a temporary delay of vaccination?' is marked as Yes and 'Date of First Delay' is equal to the 'Dose

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

				Date'. Please review and update as appropriate.
Oct-19-2020 16:14:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of First Delay: Oct/19/2020	Initial Entry

2 Treatment Name

Date	Location	User	Value	Reason
Oct-19-2020 16:14:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-19-2020 16:14:09 (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
Oct-19-2020 16:17:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020 16:09	New Information
Oct-19-2020 16:14:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020 16:14	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-19-2020 16:14:09 (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
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

Oct-19-2020 16:17:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry
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7. Route:

Date	Location	User	Value	Reason
Oct-19-2020 16:14:09 (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
Oct-19-2020 16:14:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 16:17:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Nov-17-2020 16:43:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Nov/17/2020	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: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Nov-17-2020 16:43:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-17-2020 16:43:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-18-2020 10:17:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-18-2020 04:01:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-17-2020 16:43:47 (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.
Nov-17-2020 16:43:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/17/2020	Initial Entry

5.a

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (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: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-18-2020 10:17:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPLJXF	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-18-2020 10:17:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPLJXF	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-18-2020 10:26:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRDG34	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-18-2020 10:26:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRDG34	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-18-2020 10:26:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRDG35	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-18-2020 10:26:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRDG35	Initial Entry

5.d

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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: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-18-2020 10:26:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRDG36	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Nov-18-2020 10:26:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRDG36	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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I. Date of Visit

Date	Location	User	Value	Reason
Sep-30-2020 04:09:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Sep-29-2020 15:03:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	this has been updated
Sep-28-2020 05:49:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM Query: Kindly review and complete 'Microbiology Specimen Illness Details and Nasal Swab form' at this visit. Thank you.
Sep-24-2020 14:09:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-24-2020 14:05:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Sep-24-2020 12:18:17 (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.
Sep-24-2020 12:18:17 (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.

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Sep/21/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Sep-24-2020 12:18:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/21/2020	Initial Entry
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3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Sep-24-2020 12:18:17 (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 Sep/21/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Not Complete

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Assessment:

Date	Location	User	Value	Reason
Sep-24-2020 14:05:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/21/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Sep-24-2020 14:05:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/19/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Oct-30-2020 03:01:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed as data updated.
Oct-29-2020 17:48:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	updated
Oct-29-2020 17:48:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Oct/3/2020	updated
Oct-28-2020 08:01:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM Query: Convalescent visit occurred but Date of Last Symptom Resolved is missing. Please confirm symptoms are still ongoing. If symptoms have resolved update

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

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: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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				response for Symptom ongoing as 'No' and add date resolved.
Sep-24-2020 14:05:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4 a

Date	Location	User	Value	Reason
Sep-24-2020 14:05:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Sep-24-2020 14:05:58 (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
Sep-24-2020 14:05:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Sep-24-2020 14:05:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: YES	Initial Entry

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit
on Sep/21/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951197**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39**4.b Symptoms:**

Date	Location	User	Value	Reason
Sep-24-2020 14:05:58 (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
Sep-24-2020 14:05:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Sep-24-2020 14:05:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR INCREASE D SHORTNESS OF B REATH Symptom Present: NO	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Sep-24-2020 14:05:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHORTN ESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Sep-24-2020 14:05:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Not Complete

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Oct-15-2020 08:42:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: YES	Changed Information
Sep-24-2020 14:05:58 (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
Sep-24-2020 14:05:58 (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 08:42:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Changed Information
Sep-24-2020 14:05:58 (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 08:42:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREAS s: ED MUSCLE PAIN Symptom YES Present:	Changed Information
Sep-24-2020 14:05:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREAS s: ED MUSCLE PAIN Symptom NO Present:	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020**Form Version:** 15-Sep-2020 21:55**Site No:** 1095**Subject No:** 10951197**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1095) Tekton Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39**4.e Symptoms:**

Date	Location	User	Value	Reason
Sep-24-2020 14:05:58 (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 08:42:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Changed Information
Sep-24-2020 14:05:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Sep-24-2020 14:05:58 (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
Sep-24-2020 14:05:58 (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
Sep-24-2020 14:05:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Not Complete

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-24-2020 14:05:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom s: NEW OR INCREASED SORE THROAT Symptom Present: YES	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Sep-24-2020 14:05:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Sep-24-2020 14:05:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Oct-15-2020 08:42:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom Present: YES	Changed Information
Sep-24-2020 14:05:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Not Complete

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

4.h Symptoms:

Date	Location	User	Value	Reason
Sep-24-2020 14:05:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Oct-15-2020 08:42:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Changed Information
Sep-24-2020 14:05:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Oct-15-2020 08:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITIN G Symptom Present YES :	Changed Information
Sep-24-2020 14:05:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITIN G Symptom Present NO :	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020**Form Version:** 15-Sep-2020 21:55**Site No:** 1095**Subject No:** 10951197**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1095) Tekton Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39**4.i Symptoms:**

Date	Location	User	Value	Reason
Sep-24-2020 14:05:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Oct-15-2020 08:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Changed Information
Sep-24-2020 14:05:58 (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 08:18:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: Chills	Changed Information (DELETED)
Oct-08-2020 08:41:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: Chills	Transcription Error
Oct-08-2020 08:40:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: CHills	Transcription Error
Oct-07-2020 15:37:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom chills, diarrhea, mus s - Other: cle pain and vomitin g	Transcription Error
Sep-24-2020 14:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Oth nasal congesti er: on	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951197**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39

Oct-18-2020 07:34:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Data Deleted
Oct-16-2020 08:18:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Chills	Changed Information (DELETED)
Oct-16-2020 08:18:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Changed Information
Oct-16-2020 04:38:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	DM: Thanks for response, The symptom "CHILLS" is already reported above in the predefined list. Please remove from the "Symptom-other" section. Else clarify.
Oct-15-2020 08:44:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Changed data per query
Oct-15-2020 02:07:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 3: Opened	The symptom "CHILLS" is already reported above in the predefined list. Please verify data to be updated above as "YES" for CHILLS and

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Not Complete

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Subject No: 10951197

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Generated By: (b) (4)

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

				remove from the "Symptom-other" section. Else clarify
Oct-08-2020 09:58:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 2: Closed	Discrepancy has been closed.
Oct-08-2020 08:41:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Chills	Transcription Error
Oct-08-2020 08:40:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Oct-08-2020 08:40:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHills	Transcription Error
Oct-07-2020 20:33:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 2: Opened	Multiple concepts in the term CHILLS, DIARRHEA, MUSCLE PAIN AND VOMITING. Split the term into CHILLS and DIARRHEA and MUSCLE PAIN and VOMITING and report as 4 separate entries. Thank you.

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

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Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Oct-07-2020 18:43:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-07-2020 15:37:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-07-2020 15:37:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: chills, diarrhea, muscle pain and vomiting	Transcription Error
Oct-07-2020 15:24:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	No box is checked under other but chills, diarrhea, muscle pain, vomiting also documented in the source Please add or correct where necessary; all data should match, thanks
Sep-24-2020 14:06:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: nasal congestion	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-16-2020 08:18:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: Diarrhea	Changed Information (DELETED)
Oct-08-2020 08:41:04 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Sep/21/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Not Complete

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)			Symptoms - Other: Diarrhea	
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Not Complete

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Oct-18-2020 07:34:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Data Deleted
Oct-16-2020 08:18:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Diarrhea	Changed Information (DELETED)
Oct-16-2020 08:18:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-16-2020 04:38:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Thanks for response, The symptom "Diarrhea" is already present above in the predefined list. Please remove from the "Symptom-other" section. Else clarify.
Oct-15-2020 08:44:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Oct-15-2020 02:08:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	The symptom "Diarrhea" is already present above in the predefined list. Please verify data to be updated above as "YES" for DIARRHEA and remove from the "Symptom-other" section. Else clarify.
Oct-08-2020 08:41:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Diarrhea	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Not Complete

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.c

Date	Location	User	Value	Reason
Oct-16-2020 08:18:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other muscle pain	Changed Information (DELETED)
Oct-08-2020 08:41:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other muscle pain	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Not Complete

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.c Symptoms - Other Text:

Date	Location	User	Value	Reason
Oct-18-2020 07:36:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Data deleted
Oct-16-2020 08:18:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: muscle pain	Changed Information (DELETED)
Oct-16-2020 08:18:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-16-2020 04:32:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Thanks for response, however no changes are seen. The symptom "muscle pain" is already present above in the predefined list. Please remove from the "Symptom- other" section.
Oct-15-2020 08:45:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Oct-15-2020 02:09:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	The symptom "muscle pain" is already present above in the predefined list. Please verify data to be updated above as "YES" for NEW OR INCREASED MUSCLE PAIN and remove from the "Symptom-other" section. Else clarify.
Oct-08-2020 08:41:14 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: muscle pain	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Not Complete

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)				
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5.d

Date	Location	User	Value	Reason
Oct-16-2020 08:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: vomiting	Changed Information (DELETED)
Oct-08-2020 08:41:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: vomiting	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Not Complete

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.d Symptoms - Other Text:

Date	Location	User	Value	Reason
Oct-18-2020 07:37:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Data deleted
Oct-16-2020 08:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: vomiting	Changed Information (DELETED)
Oct-16-2020 08:17:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-16-2020 04:39:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Thanks for response, The symptom "Vomiting" is already present above in the predefined list. Please remove from the "Symptom-other" section. Else clarify.
Oct-15-2020 08:45:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Oct-15-2020 02:09:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	The symptom "Vomiting" is already present above in the predefined list. Please verify data to be updated above as "YES" for VOMITING and remove from the "Symptom-other" section. Else clarify.
Oct-08-2020 08:41:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: vomiting	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail
on Sep/21/2020

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

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Date	Location	User	Value	Reason
Sep-30-2020 12:57:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	nasal swab done at site. Entered information incorrectly.
Sep-29-2020 14:58:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Sep/21/2020

Form Version: 06-Jul-2020 21:54

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

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Sep-29-2020 14:58:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/21/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Sep-29-2020 14:58:55 (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
Sep-29-2020 14:58:55 (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
Sep-29-2020 14:58:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDRO ME CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Sep-29-2020 14:58:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TES T	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Oct-07-2020 21:06:25	ACV0PFEINFP6000	Katherine	Query 1: Closed	Query closed

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Sep/21/2020

Form Version: 06-Jul-2020 21:54

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

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

(UTC-06:00) Central Time (US & Canada)		Puig (b) (4)		because site is not able to respond to query on deleted form
Oct-06-2020 08:41:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-30-2020 12:59:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-30-2020 09:28:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Trade Name and Results" are missing. Kindly review and update.

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

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: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Sep-24-2020 14:09:24 (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-24-2020 14:09:24 (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
Sep-25-2020 07:27:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-25-2020 02:54:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-24-2020 14:09:24 (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-24-2020 14:09:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/21/2020	Initial Entry

5.a

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

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: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-25-2020 07:27:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: CV17728	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-25-2020 07:27:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CV17728	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit
on Sep/21/2020**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:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951197**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-03-2020 08:24:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry
Nov-03-2020 08:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:48:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 14:59:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-03-2020 08:24:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry
Nov-03-2020 08:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:48:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 14:59:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-03-2020 14:49:06	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Clo	Auto closed by Validation Check:

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020**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:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951197**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39

(UTC-06:00) Central Time (US & Canada)			sed	VC_BEETRK001_07
Nov-03-2020 08:24:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swere d	Initial Entry
Nov-03-2020 08:24:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : NO	Initial Entry
Nov-03-2020 08:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry :	Initial Entry
Nov-03-2020 04:53:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW5244215;Sample Collected is not expected to be Not Done. Please review and update appropriately or clarify
Sep-30-2020 13:48:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Not D one	Initial Entry
Sep-29-2020 14:59:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Not A pplica ble	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Sep/21/2020

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: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Nov-03-2020 08:24:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: self swab collected	Initial Entry
Nov-03-2020 08:23:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:48:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 14:59:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Sep/21/2020

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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I.a

Date	Location	User	Value	Reason
Sep-24-2020 14:11:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Sep-24-2020 14:11:34 (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
Sep-24-2020 14:11:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Sep-24-2020 14:11:34 (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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Sep/21/2020

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Sep-24-2020 14:11:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Sep-24-2020 14:11:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.c

Date	Location	User	Value	Reason
Sep-24-2020 14:11:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Sep-24-2020 14:11:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Sep-24-2020 14:11:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
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090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Sep/21/2020

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Sep-24-2020 14:11:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner URGENT : CARE Occurrence of Visits NO or Contacts:	Initial Entry
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1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Sep-24-2020 14:11:34 (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
Sep-24-2020 14:11:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Sep-24-2020 14:11:34 (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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Sep/21/2020**Form Version:** 15-Sep-2020 21:53**Form Status:** Data Complete, Frozen, Verified**Site No:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951197**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Sep-24-2020 14:11:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Sep-24-2020 14:11:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Sep-24-2020 14:11:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTH ER Occurrence of Visits or Contacts: NO	Initial Entry

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Sep-24-2020 14:11:34 (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
Sep-24-2020 14:11:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Has the subject been hospitalized due to potential COVID-19 illness?

Date	Location	User	Value	Reason
Sep-24-2020 14:11:34 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
on Sep/21/2020

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)	(b) (4), (b) (6)
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: RESPIRATORY TREATMENT - eCRF Audit Trail History on Sep/21/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Oct-21-2020 09:16:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:07:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:49:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:00:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Oct-21-2020 09:16:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:07:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:49:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:00:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Oct-22-2020 07:25:04 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: RESPIRATORY TREATMENT - eCRF Audit Trail History on Sep/21/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)				
Oct-21-2020 09:16:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-21-2020 08:44:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	According to guidelines 8.29, this form is to be left blank if test not performed. Please clarify your request that differs from guidelines.
Oct-21-2020 02:41:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly consider to update this form if require else mark as Not applicable by selecting form level comment. Thank you.
Oct-19-2020 18:07:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:49:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:00:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Oct-21-2020 09:16:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:07:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: RESPIRATORY TREATMENT - eCRF Audit Trail History on Sep/21/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

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Generated By: (b) (4)

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

Sep-30-2020 13:49:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:00:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Oct-21-2020 09:16:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:07:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:49:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:00:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Oct-21-2020 09:16:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:07:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:49:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:00:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - eCRF Audit Trail History
on Sep/21/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Sep-30-2020 15:05:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNES S	Initial Entry
Sep-30-2020 14:15:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-29-2020 15:00:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Oct-09-2020 09:10:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-07-2020 15:41:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Diagnosis was taken from the corresponding AE that has since been deleted due to incorrect form. Initially submitted an AE prior site receiving clarification. Will get source updated and upload.
Oct-07-2020 15:27:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Term, 'Upper Respiratory Infection' is not in the source. Please provide the source, thanks
Sep-30-2020 15:05:32	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - eCRF Audit Trail History
on Sep/21/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	YES <i>Respiratory Illness Diagnosis:</i> upper respiratory infection <i>Date of Diagnosis:</i> Sep/21/2020	
Sep-30-2020 14:15:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-29-2020 15:00:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-30-2020 15:05:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry
Sep-30-2020 14:15:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-29-2020 15:00:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Sep/21/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Oct-21-2020 09:16:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Oct-21-2020 08:44:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Oct-21-2020 08:25:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Oct-19-2020 18:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-29-2020 15:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Oct-22-2020 07:25:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-21-2020 09:16:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Oct-21-2020 08:45:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	According to guidelines 8.29, this form is to be left blank if test not performed. Please clarify your request that differs from guidelines.
Oct-21-2020 08:44:58	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Sep/21/2020**Form Version:** 17-Jul-2020 21:55**Form Status:** Data Complete, Frozen**Site No:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951197**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		
Oct-21-2020 08:25:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Oct-21-2020 02:26:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly consider to update this form if require else mark as Not applicable by selecting form level comment. Thank you.
Oct-19-2020 18:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-29-2020 15:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Oct-21-2020 09:16:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Oct-21-2020 08:44:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Oct-21-2020 08:25:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Oct-19-2020 18:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-29-2020 15:00:39 (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 **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History
on Sep/21/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

4. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-21-2020 09:16:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Oct-21-2020 08:44:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Oct-21-2020 08:25:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Oct-19-2020 18:07:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-29-2020 15:00:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020**Form Version:** 21-Aug-2020 02:49**Site No:** 1095**Subject No:** 10951197**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1095) Tekton Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Oct-21-2020 09:16:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:01:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Oct-21-2020 09:16:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:01:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-22-2020 07:25:04 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)				
Oct-21-2020 09:16:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-21-2020 08:45:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	According to guidelines 8.29, this form is to be left blank if test not performed. Please clarify your request that differs from guidelines.
Oct-21-2020 02:30:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly consider to update this form if require else mark as Not applicable by selecting form level comment. Thank you.
Oct-19-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:01:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Oct-21-2020 09:16:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Sep-30-2020 13:50:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:01:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-21-2020 09:16:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id entifier: Not Done Test:: Not Applicable Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry
Oct-19-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id entifier: Not Applicable Test:: Not Applicable Result:: Not Done:: Lab Normal Range:	Initial Entry
Sep-30-2020 13:50:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id entifier: Not Done Test:: Not Applicable Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry
Sep-29-2020 15:01:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id entifier: Not Applicable Test:: Not Applicable	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

			Result::	Not Applicable
			Not Done::	Not Applicable
			Lab Normal Range:	Not Applicable

5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 09:16:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:01:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Sep-29-2020 15:01:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Oct-21-2020 09:16:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Sep-30-2020 13:50:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:01:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 09:16:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:01:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Oct-21-2020 09:16:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:01:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.b

Date	Location	User	Value	Reason
Oct-21-2020 09:16:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Applicable Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry
Oct-19-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done:: Lab Normal Range:	Initial Entry
Sep-30-2020 13:50:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Applicable Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry
Sep-29-2020 15:01:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 09:16:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:01:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Sep-29-2020 15:01:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Oct-21-2020 09:16:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:01:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Not Done:

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-21-2020 09:16:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:01:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Oct-21-2020 09:16:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:01:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-21-2020 09:16:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Applicable Result:: Not Done	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

			Not Done:: Not Done Lab Normal Range: Not Done	
Oct-19-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done:: Lab Normal Range:	Initial Entry
Sep-30-2020 13:50:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Applicable Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry
Sep-29-2020 15:01:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 09:16:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:01:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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5.c Test:

Date	Location	User	Value	Reason
Sep-29-2020 15:01:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Oct-21-2020 09:16:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep 29 2020 15 01 03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 09:16:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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Sep-30-2020 13:50:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:01:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

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

5.c LNMT

Date	Location	User	Value	Reason
Oct-21-2020 09:16:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
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Sep-29-2020 15:01:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-21-2020 09:16:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Applicable Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry
Oct-19-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done:: Lab Normal Range:	Initial Entry
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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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Oct-19-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier:	Initial Entry

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Sep-29-2020 15:01:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Not Done:

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-21-2020 09:16:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:01:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Oct-21-2020 09:16:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:01:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:51**Form Status:** Data Complete, Frozen**Site No:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951197**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-22-2020 07:25:04 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)				
Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-21-2020 08:45:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	According to guidelines 8.29, this form is to be left blank if test not performed. Please clarify your request that differs from guidelines.
Oct-21-2020 02:33:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly consider to update this form if require else mark as Not applicable by selecting form level comment. Thank you.
Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Applicable Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry
Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done:: Lab Normal Range:	Initial Entry
Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Applicable Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

			Result::	Not Applicable
			Not Done::	Not Applicable
			Lab Normal Range:	Not Applicable

5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.b

Date	Location	User	Value	Reason
Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Applicable Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry
Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done:: Lab Normal Range:	Initial Entry
Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Applicable Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b Not Done:

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Applicable Result:: Not Done	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

			Not Done:: Not Done Lab Normal Range: Not Done	
Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done:: Lab Normal Range:	Initial Entry
Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Applicable Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

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

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5.c Test:

Date	Location	User	Value	Reason
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep 29 2020 15 02 06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.c LNMT

Date	Location	User	Value	Reason
Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Applicable Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry
Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done:: Lab Normal Range:	Initial Entry
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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

			Test:: Not Applicable Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	
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Date	Location	User	Value	Reason
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5.h

Date	Location	User	Value	Reason
Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Applicable Result:: Not Done	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

			Not Done:: Not Done Lab Normal Range: Not Done	
Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done:: Lab Normal Range:	Initial Entry
Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Applicable Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

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

[Back to Form](#)

5.h				
Date	Location	User	Value	Reason
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

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Site No: 1095

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Generated By: (b) (4)

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

5.h Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.h Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry
Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry
Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.i

Date	Location	User	Value	Reason
Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier Not Done	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

			Test:: Not Applicable Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	
Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done:: Lab Normal Range:	Initial Entry
Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Applicable Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.i Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry
Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry
Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

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Form Status: Data Complete, Frozen

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Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.i Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry
Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry
Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.j

Date	Location	User	Value	Reason
Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier Not Done	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

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Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

			Test:: Not Applicable Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	
Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done:: Lab Normal Range:	Initial Entry
Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Applicable Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Site No: 1095

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

5.j Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry
Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry
Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

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Site No: 1095

Site Name: (1095) Tekton Research

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Generated By: (b) (4)

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

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5.j Result:

Date	Location	User	Value	Reason
Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep 29 2020 15 02 06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep 30 2020 13 50 27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Oct-21-2020 09:17:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

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

Sep-29-2020 15:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History on Sep/21/2020**Form Version:** 21-Aug-2020 02:50**Form Status:** Data Complete, Frozen**Site No:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951197**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Oct-22-2020 07:25:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-21-2020 09:17:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-21-2020 08:46:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	According to guidelines 8.29, this form is to be left blank if test not performed. Please clarify your request that differs from guidelines.
Oct-21-2020 03:05:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly consider to update this form if require else mark as Not applicable by selecting form level comment. Thank you.
Oct-19-2020 18:08:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:02:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Sep/21/2020

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Oct-21-2020 09:17:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Not Applicable Systolic:: Not Done Diastolic:: Not Done Respiratory Rate in respirations/minute: Not Done Heart Rate in beats/minute: Not Done	Initial Entry
Oct-19-2020 18:08:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Not Applicable Systolic:: Diastolic:: Respiratory Rate in respirations/minute: Heart Rate in beats/minute:	Initial Entry
Sep-30-2020 13:50:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Not Applicable Systolic:: Not Done Diastolic:: Not Done Respiratory Rate in respirations/minute: Not Done Heart Rate in beats/minute: Not Done	Initial Entry
Sep-29-2020 15:02:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Not Applicable Systolic:: Not Applicable Diastolic:: Not Applicable Respiratory Rate in respirations/minute: Not Applicable	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Sep/21/2020

Form Version: 21-Aug-2020 02:50

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Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

			Heart Rate in beats/mi Not Applicable	
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2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-29-2020 15:02:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Oct-21-2020 09:17:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:02:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Oct-21-2020 09:17:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:02:22	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Sep/21/2020

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	Not Applicable	
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2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Oct-21-2020 09:17:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:02:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Oct-21-2020 09:17:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:50:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:02:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020**Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:51**Form Status:** Data Complete, Frozen**Site No:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951197**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Oct-22-2020 07:25:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-21-2020 09:17:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-21-2020 08:46:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	According to guidelines 8.29, this form is to be left blank if test not performed. Please clarify your request that differs from guidelines.
Oct-21-2020 03:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly consider to update this form if require else mark as Not applicable by selecting form level comment. Thank you.
Oct-19-2020 18:08:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:51:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:02:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Oct-21-2020 09:17:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: Not Applicable Oxygen Saturation: Not Done	Initial Entry
Oct-19-2020 18:08:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: Not Applicable Oxygen Saturation:	Initial Entry
Sep-30-2020 13:51:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: Not Applicable Oxygen Saturation: Not Done	Initial Entry
Sep-29-2020 15:02:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: Not Applicable Oxygen Saturation: Not Applicable	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-29-2020 15:02:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Oct-21-2020 09:17:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:08:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:51:01 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)		(b) (4), (b) (6)		
Sep-29-2020 15:02:39 (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 Sep/21/2020

Form: OXYGENATION PARAMETERS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date Time of Assessment:

Date	Location	User	Value	Reason
Oct-22-2020 07:25:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-21-2020 09:17:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-21-2020 08:46:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	According to guidelines 8.29, this form is to be left blank if test not performed. Please clarify your request that differs from guidelines.
Oct-21-2020 02:38:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly consider to update this form if require else mark as Not applicable by selecting form level comment. Thank you.
Oct-19-2020 18:09:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:51:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:02:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
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090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History on Sep/21/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Oct-21-2020 09:17:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:09:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:51:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:02:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Oct-21-2020 09:17:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:09:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:51:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:02:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit
on Sep/21/2020**Form Version:** 06-Jul-2020 21:55**Site No:** 1095**Subject No:** 10951197**Generated By:** (b) (4)**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF
Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1095) Tekton Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Oct-21-2020 09:18:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Oct-19-2020 18:09:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:51:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:03:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-21-2020 09:18:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Oct-19-2020 18:09:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:51:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:03:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-21-2020 09:18:02 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)		(b) (4), (b) (6)		
Oct-19-2020 18:09:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:51:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:03:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Oct-22-2020 07:25:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-21-2020 09:18:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Oct-21-2020 08:46:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	According to guidelines 8.29, this form is to be left blank if test not performed. Please clarify your request that differs from guidelines.
Oct-21-2020 01:39:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly consider to update this form if require else mark as Not applicable by selecting form level comment. Thank you.

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/21/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Oct-19-2020 18:09:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:51:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:03:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Oct-21-2020 09:18:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Oct-19-2020 18:09:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:51:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:03:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Oct-21-2020 09:18:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Oct-19-2020 18:09:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:51:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Sep/21/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF
Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Sep-29-2020 15:03:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: IMAGING - eCRF Audit Trail History on Sep/21/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Assessment:

Date	Location	User	Value	Reason
Oct-22-2020 07:25:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-21-2020 09:18:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-21-2020 08:46:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	According to guidelines 8.29, this form is to be left blank if test not performed. Please clarify your request that differs from guidelines.
Oct-21-2020 02:27:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly consider to update this form if require else mark as Not applicable by selecting form level comment. Thank you.
Oct-19-2020 18:09:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:51:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:03:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
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090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: IMAGING - eCRF Audit Trail History on Sep/21/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Oct-21-2020 09:18:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:09:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:51:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:03:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Oct-21-2020 09:18:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:09:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Sep-30-2020 13:51:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:03:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Oct-21-2020 09:18:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-19-2020 18:09:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - eCRF Audit Trail History
on Sep/21/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Sep-30-2020 13:51:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Sep-29-2020 15:03:11 (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 2 - Unscheduled Visit on Dec/29/2020

Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-11-2021 06:37:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	As per site confirmation - updated PD tracker
Feb-10-2021 13:51:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Conv visit did not occur, PD written and recorded in site log
Feb-04-2021 01:24:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	PDQ: Convalescent visit is missing and 35+ days (37) have passed since COVID Illness Visit. If visit occurred record the data as a matching CONVA visit; if the visit did not occur attempt to schedule the visit and obtain the CONVA sample else clarify.
Jan-10-2021 23:47:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Jan-08-2021 13:44:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	participant did not collect swab as instructed.
Jan-08-2021 00:08:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	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.

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090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Jan-07-2021 18:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Dec-29-2020 11:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-29-2020 11:02:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Dec-29-2020 11:00:34 (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.
Dec-29-2020 11:00:34 (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.
Dec-29-2020 11:00:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/29/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Dec-29-2020 11:00:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_B	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Assessment:

Date	Location	User	Value	Reason
Dec-29-2020 11:02:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/29/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Dec-29-2020 11:02:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/27/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Jan-08-2021 14:59:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-08-2021 13:50:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	updated
Jan-08-2021 13:50:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Dec/31/2020	updated
Jan-08-2021 10:40:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Please clarify whether the reported symptoms are still ongoing? If symptoms have ended, please update 'Symptoms Ongoing' on to 'NO' and add Date

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

				of Last Symptom Resolved on the CRF.
Dec-29-2020 11:02:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Dec-29-2020 11:02:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Dec-29-2020 11:02:17 (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
Dec-29-2020 11:02:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Dec-29-2020 11:02:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms NEW OR INCREA : SED COUGH Symptom Present: NO	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete, Frozen**Site No:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951197**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39**4.b Symptoms:**

Date	Location	User	Value	Reason
Dec-29-2020 11:02:17 (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
Dec-29-2020 11:02:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Dec-29-2020 11:02:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Dec-29-2020 11:02:17 (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
Dec-29-2020 11:02:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Dec-29-2020 11:02:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: YES	Initial Entry
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4.d Symptoms:

Date	Location	User	Value	Reason
Dec-29-2020 11:02:17 (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
Dec-29-2020 11:02:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.e

Date	Location	User	Value	Reason
Dec-29-2020 11:02:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREASED MUSCLE PAIN Symptom Present: YES	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Dec-29-2020 11:02:17 (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
Dec-29-2020 11:02:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

4.f

Date	Location	User	Value	Reason
Dec-29-2020 11:02:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms NEW LOSS OF TASTE OR SMELL Symptom NO Present:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Dec-29-2020 11:02:17 (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
Dec-29-2020 11:02:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Dec-29-2020 11:02:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREASED SORE THROAT Symptom NO Present:	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020**Form Version:** 10-Dec-2020 02:29**Site No:** 1095**Subject No:** 10951197**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1095) Tekton Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39**4.g Symptoms:**

Date	Location	User	Value	Reason
Dec-29-2020 11:02:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SORE T HROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Dec-29-2020 11:02:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Dec-29-2020 11:02:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHE A Symptom Present NO :	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Dec-29-2020 11:02:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Dec-29-2020 11:02:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Dec-29-2020 11:02:17 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)		(b) (4), (b) (6)	Symptoms: VOMITIN G Symptom Present NO :	
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4.i Symptoms:

Date	Location	User	Value	Reason
Dec-29-2020 11:02:17 (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
Dec-29-2020 11:02:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-29-2020 11:02:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms - Other: elevated temp-9 ther: 9.9 F	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Jan-08-2021 14:58:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-08-2021 13:49:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Per protocol, fever defined as temp over 100.4
Jan-08-2021 10:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLIQUEY: Please clarify if Symptom- ELEVATED TEMP 99.9 F has any relation/similarity to the pre-defined

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

				symptom of FEVER. If so ELEVATED TEMP 99.9 F should be removed and FEVER updated to YES.
Dec-29-2020 11:02:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: elevated temp-99.9 F	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail
on Dec/29/2020

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Dec-29-2020 11:04:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Dec/29/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Dec-29-2020 11:21:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Dec-29-2020 11:20:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Dec-29-2020 11:04:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/29/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Dec-29-2020 11:21:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Dec-29-2020 11:21:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Dec-29-2020 11:04:44 (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
Dec-29-2020 11:21:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Dec-29-2020 11:21:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Dec-29-2020 11:04:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NASOPHARYNX	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Dec/29/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

4. Assay Code and Description:

Date	Location	User	Value	Reason
Dec-29-2020 11:21:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Done	Initial Entry
Dec-29-2020 11:20:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Dec-29-2020 11:04:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDR OME CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Dec-29-2020 11:21:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Done	Initial Entry
Dec-29-2020 11:20:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Dec-29-2020 11:04:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TES T	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Dec-29-2020 11:21:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Dec-29-2020 11:21:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
on Dec/29/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Dec-29-2020 11:21:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Dec-29-2020 11:21:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Dec-29-2020 11:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-29-2020 11:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-07-2021 18:10:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Jan-07-2021 18:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: 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.
Jan-07-2021 18:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-07-2021 18:09:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Changed Information
Dec-30-2020 01:04:00 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)				barcodes are entered. Please review and correct as appropriate.
Dec-29-2020 11:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-29-2020 11:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/29/2020	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Jan-07-2021 18:10:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-07-2021 18:10:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Spoke with participant today and she reports she did not swab. PD written.	Transcription Error
Jan-07-2021 18:10:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Entered text has either a carriage return (line break) or extra spaces at the end of the text or between words. Please correct by removing all data in the field and re-enter without adding extra spaces or using enter or tab keys.
Jan-07-2021 18:10:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Spoke with participant today and she reports she did not swab. P	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

			D written	
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Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit
on Dec/29/2020**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951197**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-29-2020 11:05:43 (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-29-2020 11:05:43 (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
Dec-29-2020 11:10:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-29-2020 11:05:43 (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.
Dec-29-2020 11:05:43 (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
Dec-29-2020 11:10:24	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

(b) (4),
(b) (6)

patient took self-swab at home

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/29/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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I.a

Date	Location	User	Value	Reason
Dec-29-2020 11:09:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-29-2020 11:09:21 (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
Dec-29-2020 11:09:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Dec-29-2020 11:09:21 (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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/29/2020**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete, Frozen**Site No:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951197**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39***I.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-29-2020 11:09:21 (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
Dec-29-2020 11:09:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.c

Date	Location	User	Value	Reason
Dec-29-2020 11:09:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-29-2020 11:09:21 (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
Dec-29-2020 11:09:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.d

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/29/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Dec-29-2020 11:09:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry
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1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-29-2020 11:09:21 (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
Dec-29-2020 11:09:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Dec-29-2020 11:09:21 (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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/29/2020**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete, Frozen**Site No:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951197**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-29-2020 11:09:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-29-2020 11:09:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Dec-29-2020 11:09:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTHER Occurrence of Visits or Contacts: NO	Initial Entry

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-29-2020 11:09:21 (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
Dec-29-2020 11:09:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Has the subject been hospitalized due to potential COVID-19 illness?

Date	Location	User	Value	Reason
Dec-29-2020 11:09:21 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
on Dec/29/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)	(b) (4), (b) (6)
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090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History on Dec/29/2020**Form Version:** 06-Jul-2020 21:53**Form Status:** Data Complete, Frozen**Site No:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951197**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. What is the treatment Identifier?**

Date	Location	User	Value	Reason
Dec-29-2020 11:11:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Dec-29-2020 11:11:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Dec-29-2020 11:11:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Dec-29-2020 11:11:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Dec-29-2020 11:11:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Dec-29-2020 11:11:39	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History
on Dec/29/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit Form: ILLNESS DETAILS - eCRF Audit Trail History on Dec/29/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Dec-29-2020 11:12:37 (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
Dec-29-2020 11:12:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Respiratory Illness Diagnosis:</i> Viral URI Date of Diagnosis: Dec/29/2020	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-29-2020 11:12:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Dec/29/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Dec-29-2020 11:15:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Dec-29-2020 11:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-29-2020 11:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

			Not Done::	Not Done
			Lab Normal Range:	Not Done

5.a Sponsor ID:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Dec-29-2020 11:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.b

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Dec-29-2020 11:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sponsor ID:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Dec-29-2020 11:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-29-2020 11:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Done
			Result::	Not Done
			Not Done::	Not Done
			Lab Normal Range:	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sponsor ID:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Dec-29-2020 11:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-29-2020 11:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

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Subject No: 10951197

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

			Test::	Not Done
			Result::	Not Done
			Not Done::	Not Done
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5.e

Date	Location	User	Value	Reason
Dec-29-2020 11:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

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			Test::	Not Done
			Result::	Not Done
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5.f

Date	Location	User	Value	Reason
Dec-29-2020 11:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

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Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

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Form Version: 21-Aug-2020 02:49

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Subject No: 10951197

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Generated By: (b) (4)

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

			Test::	Not Done	
			Result::	Not Done	
			Not Done::	Not Done	
			Lab Normal Range:	Not Done	

Header Text: c4591001

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5.f LNMT

Date	Location	User	Value	Reason
Dec-29-2020 11:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g

Date	Location	User	Value	Reason
Dec-29-2020 11:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

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Form Version: 21-Aug-2020 02:49

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Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Done
			Result::	Not Done
			Not Done::	Not Done
			Lab Normal Range:	Not Done

Header Text: c4591001

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

5.g Sponsor ID:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

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Date	Location	User	Value	Reason
Dec-29-2020 11:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

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Dec-29-2020 11:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g Not Done:

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5.g LNMT

Date	Location	User	Value	Reason
Dec-29-2020 11:15:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

			Not Done::	Not Done
			Lab Normal Range:	Not Done

5.a Sponsor ID:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.b

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

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Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

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Subject No: 10951197

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

5.b Sponsor ID:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done	Initial Entry

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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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5.e Sponsor ID:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Done
			Result::	Not Done
			Not Done::	Not Done
			Lab Normal Range:	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.f Sponsor ID:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Done	
			Result::	Not Done	
			Not Done::	Not Done	
			Lab Normal Range:	Not Done	

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.g Sponsor ID:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.h

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Done
			Result::	Not Done
			Not Done::	Not Done
			Lab Normal Range:	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.h Sponsor ID:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.i

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Done	
			Result::	Not Done	
			Not Done::	Not Done	
			Lab Normal Range:	Not Done	

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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5.i Sponsor ID:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.j

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Iden Not Do	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

				tifier:	ne
				Test::	Not Done
					ne
				Result::	Not Done
					ne
				Not Done::	Not Done
					ne
				Lab Normal Range:	Not Done
					ne

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.j Sponsor ID:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Dec-29-2020 11:15:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Dec/29/2020

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date:

Date	Location	User	Value	Reason
Dec-29-2020 11:16:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a

Date	Location	User	Value	Reason
Dec-29-2020 11:16:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Not Done Systolic:: Not Done Diastolic:: Not Done Respiratory Rate in respirations/minute: Not Done Heart Rate in beats/minute: Not Done	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Dec-29-2020 11:16:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Dec-29-2020 11:16:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
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090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
on Dec/29/2020

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Dec-29-2020 11:16:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Dec-29-2020 11:16:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Dec-29-2020 11:16:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date:

Date	Location	User	Value	Reason
Dec-29-2020 11:16:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a

Date	Location	User	Value	Reason
Dec-29-2020 11:16:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Not Done Oxygen Saturation: Not Done	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Dec-29-2020 11:16:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Dec-29-2020 11:16:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History on Dec/29/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date Time of Assessment:

Date	Location	User	Value	Reason
Dec-29-2020 11:21:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Dec-29-2020 11:21:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Dec-29-2020 11:21:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/29/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Dec-29-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Dec-29-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Dec-29-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Dec-29-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Dec-29-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Ongoing?

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit
on Dec/29/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF
Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Dec-29-2020 11:22:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit Form: IMAGING - eCRF Audit Trail History
on Dec/29/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

1. Date of Assessment:

Date	Location	User	Value	Reason
Dec-29-2020 11:22:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Dec-29-2020 11:22:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Dec-29-2020 11:22:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Dec-29-2020 11:22:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit on Jan/28/2021

Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-03-2021 04:37:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-02-2021 11:18:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	updated
Jan-29-2021 07:18:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM: Kindly consider to update missing COVID TEST form or else clarify. Thank you.
Jan-28-2021 14:50:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-28-2021 14:49:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jan-28-2021 14:49:21 (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.
Jan-28-2021 14:49:21 (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.

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Jan/28/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Jan-28-2021 14:49:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/28/2021	Initial Entry
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3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Jan-28-2021 14:49:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_C	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 3 - Unscheduled Visit
on Jan/28/2021**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
Audit Trail History**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete, Frozen**Site No:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951197**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Jan-28-2021 14:49:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/28/2021	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Jan-28-2021 14:49:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/25/2021	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Jan-28-2021 14:49:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Jan/27/2021	Initial Entry

4.a

Date	Location	User	Value	Reason
Jan-28-2021 14:49:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Jan-28-2021 14:49:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit on Jan/28/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jan-28-2021 14:49:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Jan-28-2021 14:49:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms NEW OR INCREASED COUGH Symptom NO Present:	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Jan-28-2021 14:49:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Jan-28-2021 14:49:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Jan-28-2021 14:49:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit on Jan/28/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

4.c Symptoms:

Date	Location	User	Value	Reason
Jan-28-2021 14:49:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Jan-28-2021 14:49:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Jan-28-2021 14:49:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms: CHILLS Symptom Present: YES	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Jan-28-2021 14:49:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Jan-28-2021 14:49:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

4.e

Date	Location	User	Value	Reason
Jan-28-2021 14:49:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom: NEW OR INCREASED MUSCLE PAIN	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 3 - Unscheduled Visit on Jan/28/2021**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete, Frozen**Site No:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951197**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39

			Symptom YES Present:	
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4.e Symptoms:

Date	Location	User	Value	Reason
Jan-28-2021 14:49:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Jan-28-2021 14:49:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.f

Date	Location	User	Value	Reason
Jan-28-2021 14:49:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms NEW LOSS OF TASTE OR SMELL Symptom NO Present:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Jan-28-2021 14:49:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Jan-28-2021 14:49:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit on Jan/28/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jan-28-2021 14:49:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREASED SORE THROAT Symptom YES Present:	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Jan-28-2021 14:49:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Jan-28-2021 14:49:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Jan-28-2021 14:49:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom Present NO :	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 3 - Unscheduled Visit on Jan/28/2021**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete, Frozen**Site No:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951197**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39**4.h Symptoms:**

Date	Location	User	Value	Reason
Jan-28-2021 14:49:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Jan-28-2021 14:49:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Jan-28-2021 14:49:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITIN G Symptom Present NO :	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Jan-28-2021 14:49:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Jan-28-2021 14:49:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-28-2021 14:50:13 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit on Jan/28/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)	(b) (4), (b) (6)	Symptoms - Other: elevated temp 99.9
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5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Jan-28-2021 14:50:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: elevated temp 99.9	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 3 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Jan/28/2021**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen**Site No:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951197**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Feb-03-2021 08:20:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-02-2021 11:17:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Feb-02-2021 11:17:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	updated
Feb-01-2021 16:23:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please complete the page, thanks

2. Specimen Type:

Date	Location	User	Value	Reason
Feb-02-2021 11:17:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Feb-02-2021 11:17:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Feb-02-2021 11:17:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5. Device Type:

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Jan/28/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Feb-02-2021 11:17:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Feb-02-2021 11:17:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Feb-02-2021 11:17:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Feb-02-2021 11:17:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Feb-02-2021 11:17:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 3 - Unscheduled Visit
on Jan/28/2021**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF -
eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951197**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-28-2021 14:50:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-28-2021 14:50:31 (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
Feb-02-2021 15:02:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-29-2021 02:33:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-28-2021 14:50:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-28-2021 14:50:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/28/2021	Initial Entry

5.a

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit on Jan/28/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Feb-02-2021 15:02:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: CV00540	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-02-2021 15:02:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CV00540	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit on Jan/28/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Jan-28-2021 14:50:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-28-2021 14:50:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-28-2021 14:50:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Jan-28-2021 14:50:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Participant will complete home s wab	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/28/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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I.a

Date	Location	User	Value	Reason
Jan-28-2021 14:51:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-28-2021 14:51:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-28-2021 14:51:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Jan-28-2021 14:51:16 (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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 3 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/28/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete, Frozen**Site No:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951197**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-28-2021 14:51:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-28-2021 14:51:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.c

Date	Location	User	Value	Reason
Jan-28-2021 14:51:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-28-2021 14:51:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-28-2021 14:51:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/28/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Jan-28-2021 14:51:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry
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1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-28-2021 14:51:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-28-2021 14:51:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Jan-28-2021 14:51:16 (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

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 3 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/28/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete, Frozen**Site No:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951197**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-28-2021 14:51:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-28-2021 14:51:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Jan-28-2021 14:51:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTHER Occurrence of Visits or Contacts: NO	Initial Entry

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-28-2021 14:51:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-28-2021 14:51:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Has the subject been hospitalized due to potential COVID-19 illness?

Date	Location	User	Value	Reason
Jan-28-2021 14:51:16 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
on Jan/28/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)	(b) (4), (b) (6)
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090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 3 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History on Jan/28/2021**Form Version:** 06-Jul-2020 21:53**Form Status:** Data Complete, Frozen**Site No:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951197**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. What is the treatment Identifier?**

Date	Location	User	Value	Reason
Jan-28-2021 14:51:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Jan-28-2021 14:51:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Jan-28-2021 14:51:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Jan-28-2021 14:51:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Jan-28-2021 14:51:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Jan-28-2021 14:51:31	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History
on Jan/28/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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

(b) (4),
(b) (6)

Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit Form: ILLNESS DETAILS - eCRF Audit Trail History
on Jan/28/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Jan-28-2021 14:52:29 (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
Jan-28-2021 14:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Respiratory Illness Diagnosis:</i> viral upper respiratory infectio n Date of Diagnosis: Jan/28/2021	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-28-2021 14:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Jan/28/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Jan-28-2021 14:52:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Jan-28-2021 14:52:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Jan-28-2021 14:52:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-28-2021 14:52:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 3 - Unscheduled Visit
on Jan/28/2021**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY -
eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:49**Form Status:** Data Complete, Frozen**Site No:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951197**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable Test:: Not Applicable Result:: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit on Jan/28/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

			Not Done::	Not Applicable
			Lab Normal Range :	Not Applicable

5.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit on Jan/28/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit on Jan/28/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sponsor ID:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Id Not Applicable	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit on Jan/28/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Applicable
			Result::	Not Applicable
			Not Done::	Not Applicable
			Lab Normal Range	Not Applicable
			:	

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit on Jan/28/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sponsor ID:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Id Not Applicable	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit on Jan/28/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Applicable
			Result::	Not Applicable
			Not Done::	Not Applicable
			Lab Normal Range :	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit on Jan/28/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sponsor ID:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Id Not Applicable	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit on Jan/28/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Applicable
			Result::	Not Applicable
			Not Done::	Not Applicable
			Lab Normal Range :	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit on Jan/28/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.e Sponsor ID:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Id Not Applicable	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit on Jan/28/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Applicable
			Result::	Not Applicable
			Not Done::	Not Applicable
			Lab Normal Range	Not Applicable
			:	

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit on Jan/28/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.f Sponsor ID:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Id Not Applicable	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit on Jan/28/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Applicable
			Result::	Not Applicable
			Not Done::	Not Applicable
			Lab Normal Range	Not Applicable
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Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit on Jan/28/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.g Sponsor ID:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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Jan-28-2021 14:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit on Jan/28/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit on Jan/28/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

			Not Done::	Not Applicable
			Lab Normal Range :	Not Applicable

5.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit on Jan/28/2021

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Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit on Jan/28/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sponsor ID:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
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5.b Not Done:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
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Header Text: c4591001

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Subject No: 10951197

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Generated By: (b) (4)

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

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			Not Done::	Not Applicable
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Header Text: c4591001

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5.c Not Done:

Date	Location	User	Value	Reason
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Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Applicable	Initial Entry

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

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			Result::	Not Applicable
			Not Done::	Not Applicable
			Lab Normal Range :	Not Applicable

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Date	Location	User	Value	Reason
Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Id Not Applicable	Initial Entry

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Visit: POT_COVID_ILL 3 - Unscheduled Visit on Jan/28/2021

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Site No: 1095

Site Name: (1095) Tekton Research

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Generated By: (b) (4)

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			Result::	Not Applicable
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Date	Location	User	Value	Reason
Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.i

Date	Location	User	Value	Reason
Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Id Not Applicable	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit on Jan/28/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Not Applicable
			Result::	Not Applicable
			Not Done::	Not Applicable
			Lab Normal Range :	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit on Jan/28/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

[Back to Form](#)

5.i Sponsor ID:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.j

Date	Location	User	Value	Reason
Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applic	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit on Jan/28/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

			entifier:	able	
			Test::	Not Applic able	
			Result::	Not Applic able	
			Not Done::	Not Applic able	
			Lab Normal Range	Not Applic	
			:	able	

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit on Jan/28/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.j Sponsor ID:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Jan-28-2021 14:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 3 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
on Jan/28/2021**Form Version:** 21-Aug-2020 02:50**Form Status:** Data Complete, Frozen**Site No:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951197**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Jan-28-2021 14:53:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-28-2021 14:53:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: Not Applicable Systolic:: Not Applicable Diastolic:: Not Applicable Respiratory Rate in r espirations/minute: Not Applicable Heart Rate in beats/ minute: Not Applicable	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
on Jan/28/2021

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Jan-28-2021 14:53:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Jan-28-2021 14:53:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit on Jan/28/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date:

Date	Location	User	Value	Reason
Jan-28-2021 14:54:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-28-2021 14:54:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier Not Applicable : Oxygen Saturation: Not Applicable	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-28-2021 14:54:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Jan-28-2021 14:54:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History on Jan/28/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date Time of Assessment:

Date	Location	User	Value	Reason
Jan-28-2021 14:54:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Jan-28-2021 14:54:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Jan-28-2021 14:54:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 3 - Unscheduled Visit
on Jan/28/2021**Form Version:** 06-Jul-2020 21:55**Site No:** 1095**Subject No:** 10951197**Generated By:** (b) (4)**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF
Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1095) Tekton Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Jan-28-2021 14:55:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-28-2021 14:55:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jan-28-2021 14:55:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Jan-28-2021 14:55:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Jan-28-2021 14:55:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Header Text: c4591001

Visit: POT_COVID_ILL 3 - Unscheduled Visit
on Jan/28/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF
Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jan-28-2021 14:55:01 (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 3 - Unscheduled Visit **Form:** IMAGING - eCRF Audit Trail History
on Jan/28/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Assessment:

Date	Location	User	Value	Reason
Jan-28-2021 14:55:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Jan-28-2021 14:55:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Jan-28-2021 14:55:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Jan-28-2021 14:55:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled Visit on Oct/19/2020**Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Frozen, Verified**Site No:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951197**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Date of Visit**

Date	Location	User	Value	Reason
Oct-24-2020 05:44:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-23-2020 13:41:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The visit was both a Visit 2 and a illness convalescent visit-same date.
Oct-23-2020 02:19:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW5087044;The Date of Visit at Visit COVID_A1 is the same as the other Date of Visit at Visit V2_VAX2_L. Please review for duplication and update as appropriate.
Oct-19-2020 18:10:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Oct-19-2020 18:10:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_A1	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Oct/19/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Oct-19-2020 18:11:10 (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-19-2020 18:11:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-22-2020 14:37:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Closed	Auto closed by Validation Check: VC_BEETRK001_03
Oct-22-2020 08:51:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Oct-22-2020 08:51:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/19/2020	Transcription Error

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled
Visit on Oct/19/2020**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951197**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39

Oct-22-2020 07:28:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reis sued:O pened	DM: Thanks for response. This form is for immunogenicity sample, please verify and correct date of collection. Else clarify.
Oct-21-2020 08:52:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Ans wered	self swab done at COV ILL visit 21Sep2020
Oct-21-2020 01:34:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Ope ned	DMW5086943;Date of Collection is not equal to Date of Visit. Please clarify or correct.
Oct-20-2020 16:53:57 (UTC 06 00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Clos ed	Close Auto Query
Oct-20-2020 09:46:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ope ned	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-19-2020 18:11:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Can didate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-19-2020 18:11:10 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data E ntry: YES Date	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Oct/19/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)			of Collection: Sep/21/2020
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4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Oct-21-2020 08:52:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Oct-21-2020 08:51:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: self swab done at COV ILL visit 21Sep2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-20-2020 16:53:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP1MMY	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 16:53:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP1MMY	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-20-2020 16:54:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP1MMZ	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Oct/19/2020

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

5.b Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 16:54:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP1MMZ	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-20-2020 16:54:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP1MN0	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 16:54:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BP1MN0	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-20-2020 17:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPLJSP	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 17:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPLJSP	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-20-2020 17:11:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPLJSR	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Oct/19/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.e Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 17:11:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPLJSR	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 2 - Unscheduled
Visit on Feb/26/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit
Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-26-2021 17:07:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Feb/26/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Feb-26-2021 17:07:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> COVID_C1	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 2 - Unscheduled
Visit on Feb/26/2021**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1095**Site Name:** (1095) Tekton Research**Subject No:** 10951197**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-26-2021 17:07:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-26-2021 17:07:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-03-2021 13:54:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-01-2021 05:10:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-26-2021 17:07:58 (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.
Feb-26-2021 17:07:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/26/2021	Initial Entry

5.a

Header Text: c4591001

Visit: POT_COVID_CONVA 2 - Unscheduled
Visit on Feb/26/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Mar-03-2021 13:54:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRBTJ5	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 13:54:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRBTJ5	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-03-2021 13:54:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRBTJ6	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 13:54:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRBTJ6	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-03-2021 13:54:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRBTJ7	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-03-2021 13:54:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRBTJ7	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/21/2020

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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I. Date of Visit

Date	Location	User	Value	Reason
Sep-21-2020 15:12:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/21/2020	Initial Entry

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Sep/21/2020

Form: UNPLANNED VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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I. Assessments

Date	Location	User	Value	Reason
Sep-21-2020 15:16:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-21-2020 15:12:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Sep-21-2020 15:12:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CONTACT OUTCOME	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on
Sep/21/2020**Form Version:** 22-Apr-2020 21:04**Site No:** 1095**Subject No:** 10951197**Generated By:** (b) (4)**Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail
History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1095) Tekton Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Contact Type:**

Date	Location	User	Value	Reason
Sep-21-2020 15:16:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Sep-21-2020 15:16:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Sep/21/2020 Contact Outcome: VISIT NOT ARRANGED, UN ABLE TO ATTEND	Initial Entry

3. Comments:

Date	Location	User	Value	Reason
Sep-21-2020 15:16:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Subject reports productive cough, sore throat and myalgia for 3 days. Denies fever or other symptoms. S ubject spoke with co-PI. Subject w ill do nasal swab at home as instru cted.	Initial Entry

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on Nov/02/2020

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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I. Date of Visit

Date	Location	User	Value	Reason
Nov-02-2020 13:54:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/2/2020	Initial Entry

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on Nov/02/2020

Form: UNPLANNED VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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I. Assessments

Date	Location	User	Value	Reason
Nov-02-2020 13:54:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-02-2020 13:54:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Nov-02-2020 13:54:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CONTACT OUTCOME	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on Nov/02/2020

Form Version: 22-Apr-2020 21:04

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

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1. Contact Type:

Date	Location	User	Value	Reason
Nov-02-2020 13:54:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Nov-02-2020 13:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-02-2020 13:54:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Contact Outcome' is selected as 'VISIT ARRANGED' but no 'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' form(s) is/are entered. Please review and update as appropriate.
Nov-02-2020 13:54:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Nov/2/2020 Contact Outcome: VISIT ARRANGED	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on Nov/02/2020

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date:

Date	Location	User	Value	Reason
Nov-02-2020 13:54:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/2/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-02-2020 13:54:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: 1 : Temperature: 98.1 Temperature Unit F : Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-02-2020 13:54:54 (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-02-2020 13:54:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.1	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Nov-02-2020 13:54:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on
Nov/02/2020

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

2.a Temperature Location:

Date	Location	User	Value	Reason
Nov-02-2020 13:54:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> ORAL CAVITY	Initial Entry

Header Text: c4591001**Visit:** Unplanned 2 - Unscheduled Visit on
Nov/02/2020**Form Version:** 10-Oct-2020 15:57**Site No:** 1095**Subject No:** 10951197**Generated By:** (b) (4)**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1095) Tekton Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Nov-02-2020 13:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/2/2020	Initial Entry

2. Injection Site Location

Date	Location	User	Value	Reason
Nov-02-2020 13:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

3. Injection Site Body Side:

Date	Location	User	Value	Reason
Nov-02-2020 13:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

4.a

Date	Location	User	Value	Reason
Nov-02-2020 13:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Reaction:: REDNESS Reaction Present:: NO	Initial Entry

4.a Reaction:

Date	Location	User	Value	Reason
Nov-02-2020 13:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry

4.a Reaction Present:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on Nov/02/2020

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Nov-02-2020 13:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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4.b

Date	Location	User	Value	Reason
Nov-02-2020 13:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Reaction:: SWELLIN G Reaction Present: NO :	Initial Entry

4.b Reaction:

Date	Location	User	Value	Reason
Nov-02-2020 13:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWELLING	Initial Entry

4.b Reaction Present:

Date	Location	User	Value	Reason
Nov-02-2020 13:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-02-2020 13:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: PAIN AT INJECT ION SITE Symptom Present:: NO	Initial Entry

5.a Symptom:

Date	Location	User	Value	Reason
Nov-02-2020 13:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on Nov/02/2020

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.a Symptom Present:

Date	Location	User	Value	Reason
Nov-02-2020 13:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-02-2020 13:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: FATIGUE/TIRE DNESS Symptom Pre NO sent::	Initial Entry

5.b Symptom:

Date	Location	User	Value	Reason
Nov-02-2020 13:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FATIGUE/TIREDNESS	Initial Entry

5.b Symptom Present:

Date	Location	User	Value	Reason
Nov-02-2020 13:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-02-2020 13:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: HEADACH E Symptom Present NO ::	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on Nov/02/2020

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.c Symptom:

Date	Location	User	Value	Reason
Nov-02-2020 13:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> HEADACHE	Initial Entry

5.c Symptom Present:

Date	Location	User	Value	Reason
Nov-02-2020 13:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-02-2020 13:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: VOMITIN G Symptom Present: NO :	Initial Entry

5.d Symptom:

Date	Location	User	Value	Reason
Nov-02-2020 13:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> VOMITING	Initial Entry

5.d Symptom Present:

Date	Location	User	Value	Reason
Nov-02-2020 13:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-02-2020 13:57:44 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on Nov/02/2020

Form Version: 10-Oct-2020 15:57

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

Time (US & Canada)		(b) (4), (b) (6)	Symptom:: DIARRHEA A Symptom Present: NO :
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5.e Symptom:

Date	Location	User	Value	Reason
Nov-02-2020 13:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> DIARRHEA	Initial Entry

5.e Symptom Present:

Date	Location	User	Value	Reason
Nov-02-2020 13:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.f

Date	Location	User	Value	Reason
Nov-02-2020 13:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom NEW OR WORSE :: ED MUSCLE PAIN Symptom NO Present::	Initial Entry

5.f Symptom:

Date	Location	User	Value	Reason
Nov-02-2020 13:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR WORSE ENED MUSCL E PAIN	Initial Entry

5.f Symptom Present:

Date	Location	User	Value	Reason
Nov-02-2020 13:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on Nov/02/2020

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

5.g

Date	Location	User	Value	Reason
Nov-02-2020 13:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR WORSE : NED JOINT PAIN Symptom NO Present::	Initial Entry

5.g Symptom:

Date	Location	User	Value	Reason
Nov-02-2020 13:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD JOINT P AIN	Initial Entry

5.g Symptom Present:

Date	Location	User	Value	Reason
Nov-02-2020 13:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.h

Date	Location	User	Value	Reason
Nov-02-2020 13:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: CHILLS Symptom Present:: NO	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: Unplanned 2 - Unscheduled Visit on
Nov/02/2020

Form Version: 10-Oct-2020 15:57

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

5.h Symptom:

Date	Location	User	Value	Reason
Nov-02-2020 13:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

5.h Symptom Present:

Date	Location	User	Value	Reason
Nov-02-2020 13:57:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-19-2020 08:05:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/17/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-19-2020 08:05:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-19-2020 08:05:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1095) Tekton Research

Subject Initials: ---

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

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

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Date	Location	User	Value	Reason
Oct-05-2020 14:47:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Symptom is documented on COVID illness A visit
Sep-30-2020 15:07:04 (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: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1095) Tekton Research

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Oct-29-2020 16:46:26 (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: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1095) Tekton Research

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Mar-03-2021 12:18:34 (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: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1095) Tekton Research

Subject Initials: ---

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

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

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1. Category:

Date	Location	User	Value	Reason
Sep-30-2020 15:07:04 (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
Sep-30-2020 15:07:04 (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
Oct-05-2020 15:51:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Oct-05-2020 14:47:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	AE will be deleted as symptoms are documented on COVID illness A visit
Oct-01-2020 16:54:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: Please clarify if this is the same condition for which the symptoms are already documented in the Cov-ill-A visit. If yes, this AE should be removed from the AE log.
Sep-30-2020 15:07:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: upper respiratory infection	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1095) Tekton Research

Subject Initials: ---

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

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

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-30-2020 15:07:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/19/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-05-2020 14:45:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/3/2020 UNK:UNK	New Information
Sep-30-2020 15:07:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-30-2020 15:07:04 (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
Sep-30-2020 15:07:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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.

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Header Text: c4591001

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Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1095) Tekton Research

Subject Initials: ---

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

Date	Location	User	Value	Reason
Sep-30-2020 15:07:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-06-2020 05:35:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-05-2020 14:47:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Symptom is documented on COVID illness A visit
Oct-01-2020 13:22:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	Please review "If not related to study treatment other" field, the following text was indicated in the comment field [viral infection]. Any symptoms, AEs or other key data should be collected on the appropriate page. If this is already in the predefined list above please choose the appropriate

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Header Text: c4591001

Visit: Logs - Unscheduled

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Subject No: 10951197

Generated By: (b) (4)

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Form Status: Data Complete, Deleted

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Subject Initials: ---

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

				value. Please review and update as necessary. (b) (4)
Sep-30-2020 15:07:04 (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> viral infection	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-30-2020 15:07:04 (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
Sep-30-2020 15:07:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

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Header Text: c4591001

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Subject No: 10951197

Generated By: (b) (4)

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Form Status: Data Complete, Deleted

Site Name: (1095) Tekton Research

Subject Initials: ---

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

Date	Location	User	Value	Reason
Sep-30-2020 15:07:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-05-2020 14:47:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-05-2020 14:45:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE upper respiratory infection: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Sep-30-2020 15:07:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERING/RESOLVING	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Sep-30-2020 15:07:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Oct-29-2020 16:46:26 (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
Oct-29-2020 16:46:26 (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-02-2020 15:53:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Closed	Response satisfies query
Oct-30-2020 15:24:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	updated
Oct-30-2020 15:24:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Fixed drug eruption on feet bila terally	updated
Oct-30-2020 12:08:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Reissued:Opened	GPDClin: To better understand the case, please describe the type of rash/lesion and its location, so we can decide if there is a better way to report the AE.
Oct-30-2020 10:58:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This was an eruption at the same site, diagnosed by a dermatologist. Did not occur after

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Header Text: c4591001

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Subject No: 10951197

Generated By: (b) (4)

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Form Status: Data Complete

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				first vaccine, only second vaccine.
Oct-30-2020 10:50:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 1: Opened	GPDClin: A fixed drug eruption is an eruption recurs in the same site(s) each time a drug is taken. Please clarify if this was the case. If not, pls consider a more appropriate term including symptom + location, e.g., rash at injection site, etc.
Oct-29-2020 16:46:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Fixed drug eruption	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-29-2020 16:46:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/26/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-29-2020 16:46:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-29-2020 16:46:26 (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.

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Header Text: c4591001

Visit: Logs - Unscheduled

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Subject No: 10951197

Subject Initials: ---

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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
Oct-29-2020 16:46:26 (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
Oct-29-2020 16:46:26 (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
Oct-29-2020 16:46:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-29-2020 16:46:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-29-2020 16:46:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-29-2020 16:46:26 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

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Form Status: Data Complete

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Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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Time (US & Canada)

(b) (4), (b) (6)

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-29-2020 16:46:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RECOVERED/NOT RESO LVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-29-2020 16:46:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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1. Category:

Date	Location	User	Value	Reason
Mar-03-2021 12:18:34 (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
Mar-03-2021 12:18:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-09-2021 08:00:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-08-2021 11:01:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This has been included
Mar-03-2021 20:51:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical - SAE report med history does not include the subject's fibromyalgia, which requires chronic medication. Please consider safety relevance of fibromyalgia to a pain condition, and if appropriate update SAE med Hx section
Mar-03-2021 12:18:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: exacerbation of Degenerative Di sc Disease	Initial Entry

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Header Text: c4591001

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Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1095) Tekton Research

Subject Initials: ---

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

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-03-2021 12:18:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Jan/14/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-03-2021 12:18:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date Time: Jan/15/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-03-2021 12:18:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Mar-04-2021 01:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-03-2021 12:18:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE exacerbation of Degenerative Disc Disease: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.

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Header Text: c4591001

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Subject No: 10951197

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1095) Tekton Research

Subject Initials: ---

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

<p>Mar-03-2021 12:18:34 (UTC-06:00) Central Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Data Entry: 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</p>	<p>Initial Entry</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
<p>Mar-08-2021 13:36:19 (UTC-06:00) Central Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Query 1: Closed</p>	<p>Response satisfies query</p>
<p>Mar-08-2021 11:03:04 (UTC-06:00) Central Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Data Entry: NO</p>	<p>Initial Entry</p>

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1095) Tekton Research

Subject Initials: ---

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

Mar-08-2021 11:02:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This has been updated
Mar-03-2021 23:18:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Is this adverse event the result of a study Medication Error?" is missing. Kindly review and update.

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-09-2021 04:43:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-08-2021 11:02:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This has been updated
Mar-04-2021 03:18:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2021218683 ,causality was recorded as RELATED in Safety database but was recorded as NOT RELATED in AE CRF. Please confirm correct causality.If safety update is required, please submit a ffup form.
Mar-03-2021 12:18:34 (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> DEGENERATIVE D ISC DISEASE	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (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: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-03-2021 12:18:34 (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
Mar-03-2021 12:18:34 (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
Mar-09-2021 07:59:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	discectomy performed 19Jan21
Mar-08-2021 11:02:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This has been updated
Mar-03-2021 20:48:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical - Non-drug treatment for the event is YES; SAE does not report a non-drug treatment. Please clarify which non-drug treatment, and submit to the SAE in an update
Mar-03-2021 12:18:34 (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
Mar-03-2021 12:18:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1095) Tekton Research

Subject Initials: ---

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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Mar-03-2021 12:18:34 (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
Mar-04-2021 01:21:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021218683	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-23-2021 18:19:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/23/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen

Site Name: (1095) Tekton Research

Subject Initials: ---

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

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1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Feb-23-2021 18:19:36 (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 other protocol allow ance(s) and confirmed to hav e received only placebo at Vacc ination 1/2	Initial Entry

090177e196ae2fbc\Final\Final On: 01-Apr-2021 03:50 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-23-2021 18:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/23/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-23-2021 18:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

Header Text: c4591001**Visit:** Subject Status - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1095**Subject No:** 10951197**Generated By:** (b) (4)**Form:** SUBJECT STATUS - eCRF Audit Trail History**Form Status:** Data Complete, Verified**Site Name:** (1095) Tekton Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**I. Subject Status**

Date	Location	User	Value	Reason
Nov-19-2020 14:59:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-19-2020 08:06:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This has been updated
Nov-19-2020 08:05:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Nov-19-2020 05:40:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The treatment period is defined as 1st vaccination visit through the 1-month post vaccination visit after the 2nd vaccination. Please complete treatment disposition CRF and update date of EOT to match date of visit at visit 3.
Sep-01-2020 17:50:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-01-2020 16:42:22 (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
Mar-04-2021 01:26:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-04-2021 01:24:41 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

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Form Status: Data Complete, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)		(b) (4), (b) (6)		
Mar-03-2021 12:19:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	This has been updated
Mar-03-2021 12:14:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	AE entered regarding fixed drug eruption
Mar-02-2021 04:16:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON:AER#2021218683 Exacerbation of degenerative disc disease(onset date:14Jan2021)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.
Feb-17-2021 05:14:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE Recon: A nonserious AE of Unable to walk was reported in Safety database however, missing in AE CRF. Please confirm if event indeed occurred in the subject, If so, please add in AE log.
Dec-14-2020 01:38:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	deemed erroneous
Dec-11-2020 10:42:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	DCF has been submitted.
Dec-10-2020 23:43:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	RQ2: Thank you for response. Per response, please confirm that Illness ediary entry of 30NOV2020 was deemed erroneous.
Dec-09-2020 18:36:38 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	99.4 does not warrant a COVID illness visit, per

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Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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Time (US & Canada)		(b) (4), (b) (6)		protocol temp would need to be over 100.4.
Dec-09-2020 01:44:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	RQ1: Thank you for response. Per protocol, COVID Illness Symptoms should only be reported on the COVID Illness form and not on the AE form. Please confirm if subject had Covid symptoms or Illness edairy entry of 30NOV2020 was deemed erroneous.
Dec-08-2020 00:21:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candida te	RQ1: Thank you for response. Per protocol, COVID Illness Symptoms should only be reported on the COVID Illness form and not on the AE form. Please confirm if subject had Covid symptoms or Illness edairy entry of 30NOV2020 was deemed erroneous.
Dec-07-2020 15:23:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Participant reported "fever" but upon talking to participant it was only 99.4. Therefore and AE was written but not recorded.
Dec-03-2020 12:51:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Illness eDiary: Subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 30NOV2020. But there is no COVID Illness visit reported in the database. Please clarify.
Nov-19-2020 08:05:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/17/2020	Initial Entry

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Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1095

Subject No: 10951197

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1095) Tekton Research

Subject Initials: ---

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Sep-01-2020 17:50:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/1/2020	Initial Entry
Sep-01-2020 16:42:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/1/2020	Initial Entry

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1095

Site Name: (1095) Tekton Research

Subject No: 10951197

Subject Initials: ---

Generated By: (b) (4)

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I. Casebook Signature

Date	Location	User	Value	Reason
Nov-10-2020 17:03:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry