

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/15/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11661078]
2.	Birth Date:	(b) (6)/1977
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:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/15/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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 _____
----	---	-------------------------

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Sep/15/2020
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: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[C-section]
	Start Date:	Apr/15/2020
	Ongoing:	NO End Date: Apr/15/2020

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

HIV Status

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/15/2020
2.	Weight:	[102.5]
3.	Unit:	kg
4.	Height:	[165.3]
5.	Unit:	cm
6.	Body Mass Index:	[37.5]

Vital Signs Details

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

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:51

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/15/2020
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:	

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Sep/15/2020
2.	Randomization Number:	[90631]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/15/2020
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	[BNZK65]
5.b	Sample ID	[BNZK66]
5.c	Sample ID	[BNZK67]
5.d	Sample ID	[BL9ZYY]

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/15/2020
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	[BN66D8]
-----	-----------	----------

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[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/15/2020 15:44
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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Date of Visit

			Comments
1.	Date of Visit	Oct/5/2020	
2.	Erroneous Visit		

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Oct/5/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.4]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:51

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Oct/5/2020
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:	

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/5/2020
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	[BNZK6K]
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090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/5/2020 13:59
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

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/2/2020
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	[BNZKDF]
5.b	Sample ID	[BNZKDG]
5.c	Sample ID	[BNZKDH]
5.d	Sample ID	[BLB02G]

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Dec/28/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/28/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

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

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Dec/28/2020

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Not Complete

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Dec/28/2020	
2.	Date of First Symptom Started:	Dec/18/2020	
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Dec/26/2020	Comments

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	YES
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	YES
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	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?	YES
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

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
on Dec/28/2020

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Not Complete

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Symptoms - Other

5.a	Symptoms - Other Text:	[BODY ACHES]
5.b	Symptoms - Other Text:	[FATIGUE]
5.c	Symptoms - Other Text:	[HEADACHE]
5.d	Symptoms - Other Text:	[RUNNY NOSE]
5.e	Symptoms - Other Text:	[NASAL CONGESTION]
5.f	Symptoms - Other Text:	[NAUSEA]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Dec/28/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Microbiology Specimen

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

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Dec/28/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[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:	[PATIENT FAILED TO SEND DESPITE 3+ CONTACT ATTEMPTS AND MESSAGES. PT LATER AGREED TO SWAB - BUT NEVER SENT. ALSO CONTACTED EMERGENCY PERSON 1X.]

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
on Dec/28/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[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:	[PT NOT SEEN IN-CLINIC (TELEHEALTH VISIT), THUS NO IN-CLINIC SWAB TO REPORT/NOT APPLICABLE.]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Dec/28/2020**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete, Frozen, Verified**Site No:** 1166**Site Name:** (1166) Rapid Medical Research**Subject No:** 11661078**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23[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: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	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

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT
on Dec/28/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

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

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS
on Dec/28/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Illness Details

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

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	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

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Dec/28/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

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: 15-Sep-2020 21:51

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	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	

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Dec/28/2020

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

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

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Dec/28/2020

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

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

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Dec/28/2020

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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		

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Dec/28/2020

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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		

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 15-Sep-2020 21:55

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	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	

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology on Dec/28/2020

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

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

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Dec/28/2020

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

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

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Dec/28/2020

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

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

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Dec/28/2020

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

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

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Dec/28/2020

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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		

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Dec/28/2020

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 15-Sep-2020 21:52

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	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 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Dec/28/2020

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

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

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 15-Sep-2020 21:54

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	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 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Dec/28/2020

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

Vital Signs

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

Vital Signs Details

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

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	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 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS
on Dec/28/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

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

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	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 Dec/28/2020

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

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

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING
on Dec/28/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

[Form Comments](#)

[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

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - 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: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[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_A1
----	-------------------------	----------

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - 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: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[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	[BRCX0M]
5.b	Sample ID	[BRCX0N]
5.c	Sample ID	[BRCX0P]
5.d	Sample ID	[BLB05F]

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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	[]
----	-----------	-----

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Unplanned Assessments

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

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	EXPOSURE DURING PREGNANCY	Dec/18/2020 UNK:UNK	YES	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT	
2.	AE ID:	[1]	
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[EXPOSURE DURING PREGNANCY]	
4.	Start Date Time:	Dec/18/2020 UNK:UNK	
5.	Is the adverse event still ongoing?	YES	
6.	Toxicity Grade:	Not Applicable	Comments
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: [EXPOSURE DURING PREGNANCY]	
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE	

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Medication Error

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

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Status: Incomplete, Data Complete, Deleted, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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

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

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).	[]	Comments
5.	Date:	//	

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Concomitant Medications

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

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Disposition - Treatment

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Vital Signs

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

Vital Signs Details

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

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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:	

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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?	

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (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: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Disposition - Follow-Up

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/18/2021
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: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible	Comments
----	---	--	--------------------------

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/22/2021
2.	Primary Reason for Unblinding:	OTHER If other, specify: [subj is SAE sunj and will not be able to receive vacc but still wished to be unblinded]

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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 Version: 22-Apr-2020 21:03

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Subject Status

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Mary Beth Manning	Approved	Mar-08-2021 19:04:21 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, MaryBeth, 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.

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-16-2020 09:23:38 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
1	Oct-06-2020 08:35:24 (UTC-05:00) Eastern Time (US & Canada)	Cory Kozlovich (b) (4)	Note re e-Diary: Pt erroneously reported ALLERGY sxs, NOT COVID-19 sxs. Please disregard any such entries in e-diary, per CRC on 05-OCT-2020.

Header Text: c4591001

Visit: POT_COVID_ILL 1

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Not Complete

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
3	Mar-06-2021 20:06:04 (UTC-05:00) Eastern Time (US & Canada)	Cory Kozlovich (b) (4)	PENDING CRC CLARIFICATION: NO END DATES FOR MANUALLY-ADDED AEs (I.E., AEs NOT ON THE eCRF BUT ONES REQUIRING MANUAL, LINE-ITEM ENTRY DO NOT APPEAR TO HAVE END DATES PER SOURCE).

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/28/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-15-2021 15:46:58 (UTC-05:00) Eastern Time (US & Canada)	Cory Kozlovich (b) (4)	PROTOCOL ONLY REQUIRES STANDARD OF CARE PROCEDURES. THIS SITE DOES NOT CONSIDER THIS TO BE SOC - THUS NOT REQUIRED, PER PROTOCOL. THUS, NOT DONE, YET N/A IS MORE APPLICABLE BECAUSE NOT REQUIRED (I.E., NOT SKIPPED/MISSED AS IN "ND"). <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/28/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
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Header Text: c4591001

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on Dec/28/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1166

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
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Item	Date	User	Comment
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Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

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Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
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Site No: 1166

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Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
6	Jan-15-2021 15:46:58 (UTC-05:00) Eastern Time (US & Canada)	Cory Kozlovich (b) (4)	PROTOCOL ONLY REQUIRES STANDARD OF CARE PROCEDURES. THIS SITE DOES NOT CONSIDER THIS TO BE SOC - THUS NOT REQUIRED, PER PROTOCOL. THUS, NOT DONE, YET N/A IS MORE APPLICABLE BECAUSE NOT REQUIRED (I.E., NOT SKIPPED/MISSED AS IN "ND"). <hr/> Not Applicable

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Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/28/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
7	Jan-15-2021 15:46:58 (UTC-05:00) Eastern Time (US & Canada)	Cory Kozlovich (b) (4)	PROTOCOL ONLY REQUIRES STANDARD OF CARE PROCEDURES. THIS SITE DOES NOT CONSIDER THIS TO BE SOC - THUS NOT REQUIRED, PER PROTOCOL. THUS, NOT DONE, YET N/A IS MORE APPLICABLE BECAUSE NOT REQUIRED (I.E., NOT SKIPPED/MISSED AS IN "ND"). <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/28/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
8	Jan-15-2021 15:46:58 (UTC-05:00) Eastern Time (US & Canada)	Cory Kozlovich (b) (4)	PROTOCOL ONLY REQUIRES STANDARD OF CARE PROCEDURES. THIS SITE DOES NOT CONSIDER THIS TO BE SOC - THUS NOT REQUIRED, PER PROTOCOL. THUS, NOT DONE, YET N/A IS MORE APPLICABLE BECAUSE NOT REQUIRED (I.E., NOT SKIPPED/MISSED AS IN "ND"). <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/28/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
9	Jan-15-2021 15:46:58 (UTC-05:00) Eastern Time (US & Canada)	Cory Kozlovich (b) (4)	PROTOCOL ONLY REQUIRES STANDARD OF CARE PROCEDURES. THIS SITE DOES NOT CONSIDER THIS TO BE SOC - THUS NOT REQUIRED, PER PROTOCOL. THUS, NOT DONE, YET N/A IS MORE APPLICABLE BECAUSE NOT REQUIRED (I.E., NOT SKIPPED/MISSED AS IN "ND"). <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Dec/28/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-15-2021 15:52:12 (UTC-05:00) Eastern Time (US & Canada)	Cory Kozlovich (b) (4)	PROTOCOL ONLY REQUIRES STANDARD OF CARE PROCEDURES. THIS SITE DOES NOT CONSIDER THIS TO BE SOC - THUS NOT REQUIRED, PER PROTOCOL. THUS, NOT DONE, YET N/A IS MORE APPLICABLE BECAUSE NOT REQUIRED (I.E., NOT SKIPPED/MISSED AS IN "ND"). <hr/> Not Applicable

Header Text: c4591001

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on Dec/28/2020

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[Back to Form](#)

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[Back to Form](#)

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090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
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[Back to Form](#)

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
on Dec/28/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-15-2021 15:52:45 (UTC-05:00) Eastern Time (US & Canada)	Cory Kozlovich (b) (4)	PROTOCOL ONLY REQUIRES STANDARD OF CARE PROCEDURES. THIS SITE DOES NOT CONSIDER THIS TO BE SOC - THUS NOT REQUIRED, PER PROTOCOL. THUS, NOT DONE, YET N/A IS MORE APPLICABLE BECAUSE NOT REQUIRED (I.E., NOT SKIPPED/MISSED AS IN "ND").
			Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
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[Back to Form](#)

Item	Date	User	Comment
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	Cory Kozlovich (b) (4)	PROTOCOL ONLY REQUIRES STANDARD OF CARE PROCEDURES. THIS SITE DOES NOT CONSIDER THIS TO BE SOC - THUS NOT REQUIRED, PER PROTOCOL. THUS, NOT DONE, YET N/A IS MORE APPLICABLE BECAUSE NOT REQUIRED (I.E., NOT SKIPPED/MISSED AS IN "ND"). <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Dec/28/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY -
Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1166

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Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

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1	Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	Cory Kozlovich (b) (4)	PROTOCOL ONLY REQUIRES STANDARD OF CARE PROCEDURES. THIS SITE DOES NOT CONSIDER THIS TO BE SOC - THUS NOT REQUIRED, PER PROTOCOL. THUS, NOT DONE, YET N/A IS MORE APPLICABLE BECAUSE NOT REQUIRED (I.E., NOT SKIPPED/MISSED AS IN "ND"). <hr/> Not Applicable

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

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Form Version: 15-Sep-2020 21:51

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[Back to Form](#)

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Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1166

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Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

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Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

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Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Dec/28/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY -
Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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on Dec/28/2020

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[Back to Form](#)

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[Back to Form](#)

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Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments
on Dec/28/2020

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

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Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
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Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

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1	Jan-15-2021 15:54:33 (UTC-05:00) Eastern Time (US & Canada)	Cory Kozlovich (b) (4)	PROTOCOL ONLY REQUIRES STANDARD OF CARE PROCEDURES. THIS SITE DOES NOT CONSIDER THIS TO BE SOC - THUS NOT REQUIRED, PER PROTOCOL. THUS, NOT DONE, YET N/A IS MORE APPLICABLE BECAUSE NOT REQUIRED (I.E., NOT SKIPPED/MISSED AS IN "ND"). <hr/> Not Applicable

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments
on Dec/28/2020

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
2.a	Jan-15-2021 15:54:33 (UTC-05:00) Eastern Time (US & Canada)	Cory Kozlovich (b) (4)	PROTOCOL ONLY REQUIRES STANDARD OF CARE PROCEDURES. THIS SITE DOES NOT CONSIDER THIS TO BE SOC - THUS NOT REQUIRED, PER PROTOCOL. THUS, NOT DONE, YET N/A IS MORE APPLICABLE BECAUSE NOT REQUIRED (I.E., NOT SKIPPED/MISSED AS IN "ND"). <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Dec/28/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-15-2021 15:54:52 (UTC-05:00) Eastern Time (US & Canada)	Cory Kozlovich (b) (4)	PROTOCOL ONLY REQUIRES STANDARD OF CARE PROCEDURES. THIS SITE DOES NOT CONSIDER THIS TO BE SOC - THUS NOT REQUIRED, PER PROTOCOL. THUS, NOT DONE, YET N/A IS MORE APPLICABLE BECAUSE NOT REQUIRED (I.E., NOT SKIPPED/MISSED AS IN "ND"). <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Dec/28/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
1	Jan-15-2021 15:54:52 (UTC-05:00) Eastern Time (US & Canada)	Cory Kozlovich (b) (4)	PROTOCOL ONLY REQUIRES STANDARD OF CARE PROCEDURES. THIS SITE DOES NOT CONSIDER THIS TO BE SOC - THUS NOT REQUIRED, PER PROTOCOL. THUS, NOT DONE, YET N/A IS MORE APPLICABLE BECAUSE NOT REQUIRED (I.E., NOT SKIPPED/MISSED AS IN "ND"). <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Dec/28/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
2	Jan-15-2021 15:54:52 (UTC-05:00) Eastern Time (US & Canada)	Cory Kozlovich (b) (4)	PROTOCOL ONLY REQUIRES STANDARD OF CARE PROCEDURES. THIS SITE DOES NOT CONSIDER THIS TO BE SOC - THUS NOT REQUIRED, PER PROTOCOL. THUS, NOT DONE, YET N/A IS MORE APPLICABLE BECAUSE NOT REQUIRED (I.E., NOT SKIPPED/MISSED AS IN "ND"). <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Dec/28/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
3	Jan-15-2021 15:54:52 (UTC-05:00) Eastern Time (US & Canada)	Cory Kozlovich (b) (4)	PROTOCOL ONLY REQUIRES STANDARD OF CARE PROCEDURES. THIS SITE DOES NOT CONSIDER THIS TO BE SOC - THUS NOT REQUIRED, PER PROTOCOL. THUS, NOT DONE, YET N/A IS MORE APPLICABLE BECAUSE NOT REQUIRED (I.E., NOT SKIPPED/MISSED AS IN "ND"). <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Dec/28/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS -
Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-15-2021 15:55:09 (UTC-05:00) Eastern Time (US & Canada)	Cory Kozlovich (b) (4)	PROTOCOL ONLY REQUIRES STANDARD OF CARE PROCEDURES. THIS SITE DOES NOT CONSIDER THIS TO BE SOC - THUS NOT REQUIRED, PER PROTOCOL. THUS, NOT DONE, YET N/A IS MORE APPLICABLE BECAUSE NOT REQUIRED (I.E., NOT SKIPPED/MISSED AS IN "ND"). <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
1	Jan-15-2021 15:55:09 (UTC-05:00) Eastern Time (US & Canada)	Cory Kozlovich (b) (4)	PROTOCOL ONLY REQUIRES STANDARD OF CARE PROCEDURES. THIS SITE DOES NOT CONSIDER THIS TO BE SOC - THUS NOT REQUIRED, PER PROTOCOL. THUS, NOT DONE, YET N/A IS MORE APPLICABLE BECAUSE NOT REQUIRED (I.E., NOT SKIPPED/MISSED AS IN "ND"). <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Dec/28/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS -
Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
2	Jan-15-2021 15:55:09 (UTC-05:00) Eastern Time (US & Canada)	Cory Kozlovich (b) (4)	PROTOCOL ONLY REQUIRES STANDARD OF CARE PROCEDURES. THIS SITE DOES NOT CONSIDER THIS TO BE SOC - THUS NOT REQUIRED, PER PROTOCOL. THUS, NOT DONE, YET N/A IS MORE APPLICABLE BECAUSE NOT REQUIRED (I.E., NOT SKIPPED/MISSED AS IN "ND"). <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Dec/28/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS -
Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
3	Jan-15-2021 15:55:09 (UTC-05:00) Eastern Time (US & Canada)	Cory Kozlovich (b) (4)	PROTOCOL ONLY REQUIRES STANDARD OF CARE PROCEDURES. THIS SITE DOES NOT CONSIDER THIS TO BE SOC - THUS NOT REQUIRED, PER PROTOCOL. THUS, NOT DONE, YET N/A IS MORE APPLICABLE BECAUSE NOT REQUIRED (I.E., NOT SKIPPED/MISSED AS IN "ND"). <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Dec/28/2020

Form Version: 06-Jul-2020 21:55

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS -
Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
4	Jan-15-2021 15:55:09 (UTC-05:00) Eastern Time (US & Canada)	Cory Kozlovich (b) (4)	PROTOCOL ONLY REQUIRES STANDARD OF CARE PROCEDURES. THIS SITE DOES NOT CONSIDER THIS TO BE SOC - THUS NOT REQUIRED, PER PROTOCOL. THUS, NOT DONE, YET N/A IS MORE APPLICABLE BECAUSE NOT REQUIRED (I.E., NOT SKIPPED/MISSED AS IN "ND"). <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Dec/28/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS -
Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
5	Jan-15-2021 15:55:09 (UTC-05:00) Eastern Time (US & Canada)	Cory Kozlovich (b) (4)	PROTOCOL ONLY REQUIRES STANDARD OF CARE PROCEDURES. THIS SITE DOES NOT CONSIDER THIS TO BE SOC - THUS NOT REQUIRED, PER PROTOCOL. THUS, NOT DONE, YET N/A IS MORE APPLICABLE BECAUSE NOT REQUIRED (I.E., NOT SKIPPED/MISSED AS IN "ND"). <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Dec/28/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS -
Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
6	Jan-15-2021 15:55:09 (UTC-05:00) Eastern Time (US & Canada)	Cory Kozlovich (b) (4)	PROTOCOL ONLY REQUIRES STANDARD OF CARE PROCEDURES. THIS SITE DOES NOT CONSIDER THIS TO BE SOC - THUS NOT REQUIRED, PER PROTOCOL. THUS, NOT DONE, YET N/A IS MORE APPLICABLE BECAUSE NOT REQUIRED (I.E., NOT SKIPPED/MISSED AS IN "ND"). <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Dec/28/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-15-2021 15:55:30 (UTC-05:00) Eastern Time (US & Canada)	Cory Kozlovich (b) (4)	PROTOCOL ONLY REQUIRES STANDARD OF CARE PROCEDURES. THIS SITE DOES NOT CONSIDER THIS TO BE SOC - THUS NOT REQUIRED, PER PROTOCOL. THUS, NOT DONE, YET N/A IS MORE APPLICABLE BECAUSE NOT REQUIRED (I.E., NOT SKIPPED/MISSED AS IN "ND"). <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Dec/28/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
1	Jan-15-2021 15:55:30 (UTC-05:00) Eastern Time (US & Canada)	Cory Kozlovich (b) (4)	PROTOCOL ONLY REQUIRES STANDARD OF CARE PROCEDURES. THIS SITE DOES NOT CONSIDER THIS TO BE SOC - THUS NOT REQUIRED, PER PROTOCOL. THUS, NOT DONE, YET N/A IS MORE APPLICABLE BECAUSE NOT REQUIRED (I.E., NOT SKIPPED/MISSED AS IN "ND"). <hr/> Not Applicable

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Dec/28/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
2	Jan-15-2021 15:55:30 (UTC-05:00) Eastern Time (US & Canada)	Cory Kozlovich (b) (4)	PROTOCOL ONLY REQUIRES STANDARD OF CARE PROCEDURES. THIS SITE DOES NOT CONSIDER THIS TO BE SOC - THUS NOT REQUIRED, PER PROTOCOL. THUS, NOT DONE, YET N/A IS MORE APPLICABLE BECAUSE NOT REQUIRED (I.E., NOT SKIPPED/MISSED AS IN "ND"). <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Dec/28/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
3	Jan-15-2021 15:55:30 (UTC-05:00) Eastern Time (US & Canada)	Cory Kozlovich (b) (4)	PROTOCOL ONLY REQUIRES STANDARD OF CARE PROCEDURES. THIS SITE DOES NOT CONSIDER THIS TO BE SOC - THUS NOT REQUIRED, PER PROTOCOL. THUS, NOT DONE, YET N/A IS MORE APPLICABLE BECAUSE NOT REQUIRED (I.E., NOT SKIPPED/MISSED AS IN "ND"). <hr/> Not Applicable

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Dec/28/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
4	Jan-15-2021 15:55:30 (UTC-05:00) Eastern Time (US & Canada)	Cory Kozlovich (b) (4)	PROTOCOL ONLY REQUIRES STANDARD OF CARE PROCEDURES. THIS SITE DOES NOT CONSIDER THIS TO BE SOC - THUS NOT REQUIRED, PER PROTOCOL. THUS, NOT DONE, YET N/A IS MORE APPLICABLE BECAUSE NOT REQUIRED (I.E., NOT SKIPPED/MISSED AS IN "ND"). <hr/> Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-04-2021 10:18:11 (UTC-05:00) Eastern Time (US & Canada)	Cory Kozlovich (b) (4)	GRADE NOT APPLICABLE PER PROTOCOL (SECTION 8.50.2.5/8.3.5.1).
Form	Dec-30-2020 10:24:05 (UTC-05:00) Eastern Time (US & Canada)	Cory Kozlovich (b) (4)	GRADE NOT APPLICABLE PER PROTOCOL (SECTION 8.50.2.5).

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
6	Dec-30-2020 10:14:32 (UTC-05:00) Eastern Time (US & Canada)	Cory Kozlovich (b) (4)	GRADE NOT APPLICABLE PER PROTOCOL (SECTION 8.50.2.5). <hr/> Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Incomplete, Data Complete, Deleted, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

[Back to Form](#)

Item	Date	User	Comment
4	Oct-06-2020 08:41:45 (UTC-05:00) Eastern Time (US & Canada)	Cory Kozlovich (b) (4)	Awaiting clarification of dose: LOESTRIN FE brand is available as 1.5/30 AND 1/20. Requested CRC to clarify w/pt on 06-OCT-2020.

Header Text: c4591001

Visit: Potential ReVax Initial Contact

Form Version: 10-Dec-2020 02:25

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - Comments

Form Status: Data Complete, Frozen

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Item	Date	User	Comment
1	Feb-26-2021 14:03:35 (UTC-05:00) Eastern Time (US & Canada)	Cory Kozlovich (b) (4)	PARTICIPANT NOT ELIGIBLE DUE TO SAE/EXPOSURE DURING PREGNANCY. PARTICIPANT IS CONFIRMED PREGNANT AND THUS NOT ELIGIBLE FOR REVAX.

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Mary Beth Manning	Approved	Mar-08-2021 19:04:21 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

(b) (6)	N/A	Mar-05-2021 09:06:00 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mary Beth Manning	Approved	Mar-03-2021 20:29:58 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, MaryBeth, 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.

Cory Kozlovich	N/A	Feb-15-2021 11:54:18 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mary Beth Manning	Approved	Jan-21-2021 12:44:11 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Affidavit:

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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.

Cory Kozlovich	N/A	Dec-30-2020 10:07:27 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mary Beth Manning	Approved	Nov-11-2020 12:27:46 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, MaryBeth, 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.

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-16-2020 09:22:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 09:22:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Sep-16-2020 09:23:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Sep/15/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Sep-16-2020 09:22:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11661078	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-16-2020 09:22:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1977	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-16-2020 09:23:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-16-2020 09:23:22 (UTC-05:00) Eastern 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-16-2020 09:23:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Oct-08-2020 10:35:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	per response reported in error.
Oct-07-2020 08:14:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Query 1: Answered	Patient reported erroneously, please delete answer: this was an allergy symptom ONLY and not related to IP. CRC re-educated pt on e-diary use for COVID-19 sxs only.
Oct-07-2020 06:54:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	As per Illness ediary records, subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 02OCT2020. But there is no COVID Illness visit reported in the database. Please clarify.
Sep-16-2020 09:23:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/15/2020	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-16-2020 09:27:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/15/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-16-2020 09:27:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-16-2020 09:27:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1.a

Date	Location	User	Value	Reason
Sep-16-2020 09:34:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Te C-section rm: Start Date: Apr/15/2020 Ongoing: NO End Date: Apr/15/2020	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-16-2020 09:34:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 09:34:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C-section	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Sep-16-2020 09:34:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Apr/15/2020	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Sep-16-2020 09:34:54 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Time (US & Canada)			End Date:	
			Apr/15/2020	

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

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

Date	Location	User	Value	Reason
Sep-16-2020 09:28:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-16-2020 09:28:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/15/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-16-2020 09:28:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 102.5	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-16-2020 09:28:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-16-2020 09:28:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 165.3	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-16-2020 09:28:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-16-2020 09:28:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 37.5	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

7.a

Date	Location	User	Value	Reason
Sep-16-2020 09:28:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: 1 : Temperature: 98.5 Temperature Unit: F Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-16-2020 09:28:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-16-2020 09:28:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.5	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-16-2020 09:28:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-16-2020 09:28:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Sep-16-2020 09:27:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-16-2020 09:27:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-16-2020 09:27:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/15/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-16-2020 09:27:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-16-2020 09:27:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-16-2020 09:27:54 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Time (US & Canada)			Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-16-2020 09:27:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-16-2020 09:27:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-16-2020 09:27:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Sep-16-2020 09:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/15/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-16-2020 09:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 90631	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-17-2020 10:06:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-17-2020 10:06:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-17-2020 10:06:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-17-2020 10:06:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-17-2020 10:06:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/15/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-17-2020 10:06:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNZK65	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (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: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.a Sample ID

Date	Location	User	Value	Reason
Sep-17-2020 10:06:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BNZK65	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-17-2020 10:06:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BNZK66	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-17-2020 10:06:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BNZK66	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-17-2020 10:06:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BNZK67	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-17-2020 10:06:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BNZK67	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-17-2020 10:06:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BL9ZYY	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (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: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.d Sample ID

Date	Location	User	Value	Reason
Sep-17-2020 10:06:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: BL9ZYY	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: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-16-2020 09:31:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-16-2020 09:31:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-16-2020 09:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-16-2020 09:31:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-16-2020 09:31:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/15/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-16-2020 09:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN66D8	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (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: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.a Sample ID

Date	Location	User	Value	Reason
Sep-16-2020 09:31:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: BN66D8	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-16-2020 09:33:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-16-2020 09:33:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-16-2020 09:33:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-16-2020 09:33:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/15/2020 15:44	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-16-2020 09:33:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-16-2020 09:33:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

7. Route:

Date	Location	User	Value	Reason
Sep-16-2020 09:33:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-16-2020 09:33:09 (UTC-05:00) Eastern 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-16-2020 09:33:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: YES	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-16-2020 09:34:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Oct-06-2020 08:32:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Oct/5/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Oct-06-2020 08:32:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Oct/5/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-06-2020 08:32:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Record Identifier 1 :: Temperature: 98.4 Temperature Unit: F Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-06-2020 08:32:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Oct-06-2020 08:32:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: 98.4	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-06-2020 08:32:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: F	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

2.a Temperature Location:

Date	Location	User	Value	Reason
Oct-06-2020 08:32:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Oct-06-2020 08:32:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Oct-06-2020 08:32:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-06-2020 08:32:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Oct/5/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Oct-06-2020 08:32:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Oct-06-2020 08:32:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Oct-06-2020 08:32:53 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Time (US & Canada)			Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-06-2020 08:32:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-06-2020 08:32:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Oct-06-2020 08:32:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (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: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Oct-06-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-06-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-06-2020 08:33:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-06-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-06-2020 08:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: YES Date of Collection: Oct/5/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-16-2020 13:01:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Sample ID: BNZK6K	Transcription Error

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (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: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Oct-06-2020 08:33:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Sample ID: BN2K6K	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Oct-18-2020 06:16:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-16-2020 13:01:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: BNZK6K	Transcription Error
Oct-16-2020 12:57:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Query 1: Answered	Changed data per query
Oct-16-2020 07:58:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	HOLDS: The correct barcode is BNZK6K instead of BN2K6K. Please consider to verify and update.
Oct-06-2020 08:33:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: BN2K6K	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-06-2020 08:33:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-06-2020 08:33:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-06-2020 08:33:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-06-2020 08:33:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Oct/5/2020 13:59	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-06-2020 08:33:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-06-2020 08:33:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: LEFT	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

7. Route:

Date	Location	User	Value	Reason
Oct-06-2020 08:33:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-06-2020 08:33:41 (UTC-05:00) Eastern 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-06-2020 08:33:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: YES	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Nov-03-2020 09:05:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Nov/2/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Nov-03-2020 09:06:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-03-2020 09:06:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-09-2020 14:30:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-04-2020 05:37:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-03-2020 09:06:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-03-2020 09:06:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: YES Date of Collection: Nov/2/2020	Initial Entry

5.a

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Date	Location	User	Value	Reason
Nov-09-2020 14:30:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	<u>Data Entry:</u> Sample ID: BNZKDF	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-09-2020 14:30:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	<u>Data Entry:</u> BNZKDF	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-09-2020 14:30:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	<u>Data Entry:</u> Sample ID: BNZKDG	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-09-2020 14:30:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	<u>Data Entry:</u> BNZKDG	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-09-2020 14:30:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	<u>Data Entry:</u> Sample ID: BNZKDH	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-09-2020 14:30:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	<u>Data Entry:</u> BNZKDH	Initial Entry

5.d

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Date	Location	User	Value	Reason
Nov-09-2020 14:30:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Sample ID: BLB02G	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Nov-09-2020 14:30:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: BLB02G	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

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: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Feb-16-2021 02:37:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	As per site confirmation - updated PD tracker
Feb-16-2021 00:54:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-15-2021 11:54:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Query 3: Answered	SITE HAS BEEN UNSUCCESSFUL IN REACHING PATIENT/PATIENT NON-RESPONSIVE DESPITE OVER 3 ATTEMPTS TO CONTACT. SITE WILL SEND LETTER VIA USPS CERTIFIED MAIL SERVICE.
Feb-15-2021 11:53:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Query 1: Answered	SITE HAS BEEN UNSUCCESSFUL IN REACHING PATIENT/PATIENT NON-RESPONSIVE DESPITE OVER 3 ATTEMPTS TO CONTACT. SITE WILL SEND LETTER VIA USPS CERTIFIED MAIL SERVICE.
Feb-04-2021 22:42:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	PDQ: Convalescent visit is missing and 35+ days (38) have passed since COVID Illness Visit. If visit occurred record the data as a matching

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

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: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

				CONVA visit; if the visit did not occur attempt to schedule the visit and obtain the CONVA sample else clarify.
Jan-19-2021 05:00:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: 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.
Jan-15-2021 15:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jan-15-2021 15:43:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Jan-15-2021 15:43:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Jan-15-2021 15:43:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Dec/28/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Jan-15-2021 15:43:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Not Complete

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Date of Assessment:

Date	Location	User	Value	Reason
Jan-15-2021 15:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Dec/28/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Jan-15-2021 15:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Dec/18/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Mar-08-2021 09:10:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-06-2021 19:58:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: NO Date of Last Symptom Resolved: Dec/26/2020	New Information
Mar-05-2021 09:05:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This is correct, however sxs. were not reported until the 28th. Thanks
Mar-05-2021 08:59:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per convalescent visit source, all symptoms resolved on 26 Dec 2020. Please review and reconcile.
Jan-15-2021 15:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: YES	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Not Complete

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

4.a

Date	Location	User	Value	Reason
Feb-15-2021 11:54:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Symptoms: FEVER Symptom Present: YES	Transcription Error
Jan-15-2021 15:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Jan-15-2021 15:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Feb-16-2021 08:25:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-15-2021 11:54:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-15-2021 11:54:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: YES	Transcription Error
Jan-27-2021 10:41:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per progress note, subject experienced fever. If confirmed please ensure illness visit source and EDC are updated accordingly.
Jan-15-2021 15:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: NO	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Not Complete

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

4.b

Date	Location	User	Value	Reason
Jan-15-2021 15:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Symptoms NEW OR INCREASED COUGH Symptom YES Present:	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Jan-15-2021 15:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Jan-15-2021 15:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Jan-15-2021 15:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020**Form Version:** 14-Jan-2021 02:23**Site No:** 1166**Subject No:** 11661078**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:** (1166) Rapid Medical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23**4.c Symptoms:**

Date	Location	User	Value	Reason
Jan-15-2021 15:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Jan-15-2021 15:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Jan-15-2021 15:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Symptoms: CHILLS Symptom Present: YES	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Jan-15-2021 15:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Jan-15-2021 15:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: YES	Initial Entry

4.e

Date	Location	User	Value	Reason
Jan-15-2021 15:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Symptom: NEW OR INCREASED MUSCLE PAIN	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Not Complete

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			Symptom YES Present:	
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4.e Symptoms:

Date	Location	User	Value	Reason
Jan-15-2021 15:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Jan-15-2021 15:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: YES	Initial Entry

4.f

Date	Location	User	Value	Reason
Jan-15-2021 15:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Symptom NEW LOSS OF TASTE OR SMELL Symptom YES Present:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Jan-15-2021 15:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Jan-15-2021 15:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: YES	Initial Entry

4.g

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090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Not Complete

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Date	Location	User	Value	Reason
Jan-15-2021 15:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Symptom NEW OR INCREASED SORE THROAT Symptom YES Present:	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Jan-15-2021 15:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Jan-15-2021 15:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Jan-15-2021 15:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Symptoms: DIARRHEA Symptom Present YES :	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Not Complete

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

4.h Symptoms:

Date	Location	User	Value	Reason
Jan-15-2021 15:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Jan-15-2021 15:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: YES	Initial Entry

4.i

Date	Location	User	Value	Reason
Jan-15-2021 15:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Symptoms: VOMITIN G Symptom Present YES :	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020**Form Version:** 14-Jan-2021 02:23**Site No:** 1166**Subject No:** 11661078**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:** (1166) Rapid Medical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23**4.i Symptoms:**

Date	Location	User	Value	Reason
Jan-15-2021 15:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Feb-16-2021 08:26:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-15-2021 11:55:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Query 1: Answered	OTHER SYMPTOMS ADDED, PER QUERY.
Jan-27-2021 10:44:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per progress note, subject also experienced: body aches, fatigue, headache, runny nose, nasal congestion, and nausea. If confirmed please add to "other symptoms" section.
Jan-15-2021 15:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: YES	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-15-2021 11:55:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Symptoms - Other: BODY ACHES	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 Dec/28/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Not Complete

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Feb-15-2021 11:55:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: BODY ACHES	Initial Entry
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5.b

Date	Location	User	Value	Reason
Feb-15-2021 11:55:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Symptoms - Other: FATIGUE	Initial Entry

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Feb-15-2021 11:55:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: FATIGUE	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-15-2021 11:55:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Symptoms - Othe HEADACH r: E	Initial Entry

5.c Symptoms - Other Text:

Date	Location	User	Value	Reason
Feb-15-2021 11:55:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: HEADACHE	Initial Entry

5.d

Date	Location	User	Value	Reason
Feb-15-2021 11:55:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Symptoms - Oth RUNNY NO er: SE	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Not Complete

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.d Symptoms - Other Text:

Date	Location	User	Value	Reason
Feb-15-2021 11:55:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: RUNNY NOSE	Initial Entry

5.e

Date	Location	User	Value	Reason
Feb-15-2021 11:56:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Symptoms - Other: NASAL CONGESTION	Initial Entry

5.e Symptoms - Other Text:

Date	Location	User	Value	Reason
Feb-15-2021 11:56:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: NASAL CONGESTION	Initial Entry

5.f

Date	Location	User	Value	Reason
Feb-15-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Symptoms - Other: NAUSEA	Initial Entry

5.f Symptoms - Other Text:

Date	Location	User	Value	Reason
Feb-15-2021 11:56:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: NAUSEA	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Actual Date of Collection:

Date	Location	User	Value	Reason
Jan-15-2021 15:46:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jan-15-2021 15:46:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Jan-15-2021 15:46:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Jan-15-2021 15:46:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Jan-15-2021 15:46:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Jan-15-2021 15:46:58 (UTC-05:00) Eastern	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
on Dec/28/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Time (US & Canada)				
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7. Test Result:

Date	Location	User	Value	Reason
Jan-15-2021 15:46:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Jan-15-2021 15:46:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Jan-15-2021 15:46:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

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: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jan-15-2021 15:48:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-15-2021 15:48:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-15-2021 15:48:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	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
Jan-15-2021 15:48:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: PATIENT FAILED TO SEND D ESPITE 3+ CONTACT ATTEM PTS AND MESSAGES. PT LA TER AGREED TO SWAB - BU T NEVER SENT. ALSO CONT ACTED EMERGENCY PERSO N IX.	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

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: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jan-15-2021 15:48:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-15-2021 15:48:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-15-2021 15:48:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	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
Jan-15-2021 15:48:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: PT NOT SEEN IN-CLINIC (TE LEHEALTH VISIT), THUS NO IN-CLINIC SWAB TO REPOR T/NOT APPLICABLE.	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/28/2020

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1.a

Date	Location	User	Value	Reason
Jan-15-2021 15:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-15-2021 15:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-15-2021 15:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: NO	Initial Entry

1.b

Date	Location	User	Value	Reason
Jan-15-2021 15:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/28/2020**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete, Frozen, Verified**Site No:** 1166**Site Name:** (1166) Rapid Medical Research**Subject No:** 11661078**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-15-2021 15:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-15-2021 15:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: NO	Initial Entry

1.c

Date	Location	User	Value	Reason
Jan-15-2021 15:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	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-15-2021 15:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-15-2021 15:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/28/2020

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Jan-15-2021 15:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	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-15-2021 15:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-15-2021 15:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Jan-15-2021 15:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/28/2020**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete, Frozen, Verified**Site No:** 1166**Site Name:** (1166) Rapid Medical Research**Subject No:** 11661078**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-15-2021 15:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: TELEPHONE CONSULTATIO N	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-15-2021 15:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Jan-15-2021 15:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	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
Jan-15-2021 15:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-15-2021 15:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: NO	Initial Entry

3. Has the subject been hospitalized due to potential COVID-19 illness?

Date	Location	User	Value	Reason
Jan-15-2021 15:51:53 (UTC-05:00) Eastern	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
on Dec/28/2020

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Time (US & Canada)				
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090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: RESPIRATORY TREATMENT - eCRF Audit Trail History on Dec/28/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Jan-15-2021 15:52:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Jan-15-2021 15:52:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Jan-15-2021 15:52:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Jan-15-2021 15:52:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Jan-15-2021 15:52:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Jan-15-2021 15:52:12 (UTC-05:00) Eastern	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History
on Dec/28/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Time (US & Canada)				
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090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History
on Dec/28/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Jan-15-2021 15:52:30 (UTC-05:00) Eastern 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-15-2021 15:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-15-2021 15:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: 1	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Dec/28/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Jan-15-2021 15:52:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Jan-15-2021 15:52:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Jan-15-2021 15:52:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-15-2021 15:52:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020**Form Version:** 15-Sep-2020 21:51**Site No:** 1166**Subject No:** 11661078**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1166) Rapid Medical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Sponsor-Defined I Not Appli dentifier: cable Test:: Not Appli cable Result:: Not Appli cable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			Not Done:: Not Applicable Lab Normal Range : Not Applicable	
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5.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.b

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	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 1 - Unscheduled Visit on Dec/28/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.b Sponsor ID:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range :	Not Applicable	

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020**Form Version:** 15-Sep-2020 21:51**Site No:** 1166**Subject No:** 11661078**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1166) Rapid Medical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range :	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

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Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.d Sponsor ID:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range :	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.e Sponsor ID:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range :	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.f Sponsor ID:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

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Form Version: 15-Sep-2020 21:51

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Site No: 1166

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range :	Not Applicable	

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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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5.g Not Done:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Jan-15-2021 15:53:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020**Form Version:** 15-Sep-2020 21:55**Site No:** 1166**Subject No:** 11661078**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1166) Rapid Medical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Sponsor-Defined I Not Appli dentifier: cable Test:: Not Appli cable Result:: Not Appli cable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			Not Done:: Not Applicable Lab Normal Range : Not Applicable	
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5.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.b

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	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 1 - Unscheduled Visit on Dec/28/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.b Sponsor ID:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

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Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range :	Not Applicable	

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020**Form Version:** 15-Sep-2020 21:55**Site No:** 1166**Subject No:** 11661078**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1166) Rapid Medical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

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Site No: 1166

Site Name: (1166) Rapid Medical Research

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range :	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

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5.d Sponsor ID:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

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			Result::	Not Applicable	
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Date	Location	User	Value	Reason
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Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.h

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range :	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.h Sponsor ID:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.i

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Sponsor-Defined Identifier: Not Applicable	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			Test::	Not Applicable	
			Result::	Not Applicable	
			Not Done::	Not Applicable	
			Lab Normal Range :	Not Applicable	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

5.i Sponsor ID:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.j

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Sponsor-Defined I Not Appli	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			dentifier:	cabl
			Test::	Not Appli cabl
			Result::	Not Appli cabl
			Not Done::	Not Appli cabl
			Lab Normal Range	Not Appli
			:	cabl

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

Form Version: 15-Sep-2020 21:55

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

5.j Sponsor ID:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Jan-15-2021 15:53:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History on Dec/28/2020**Form Version:** 15-Sep-2020 21:52**Form Status:** Data Complete, Frozen, Verified**Site No:** 1166**Site Name:** (1166) Rapid Medical Research**Subject No:** 11661078**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Jan-15-2021 15:54:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-15-2021 15:54:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Record Identifier:: Not Ap plicable Systolic:: Not Ap plicable Diastolic:: Not Ap plicable Respiratory Rate in r espirations/minute: plicable Heart Rate in beats/ minute: Not Ap plicable	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-15-2021 15:54:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Jan-15-2021 15:54:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	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 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
on Dec/28/2020

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Jan-15-2021 15:54:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry
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2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Jan-15-2021 15:54:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Jan-15-2021 15:54:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Jan-15-2021 15:54:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-15-2021 15:54:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Record Identifier: Not Applicable Oxygen Saturation: Not Applicable	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-15-2021 15:54:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Jan-15-2021 15:54:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History on Dec/28/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Date Time of Assessment:

Date	Location	User	Value	Reason
Jan-15-2021 15:54:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Jan-15-2021 15:54:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Jan-15-2021 15:54:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit
on Dec/28/2020**Form Version:** 06-Jul-2020 21:55**Site No:** 1166**Subject No:** 11661078**Generated By:** (b) (4)**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF
Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1166) Rapid Medical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23[Back to Form](#)**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Jan-15-2021 15:55:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-15-2021 15:55:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jan-15-2021 15:55:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	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-15-2021 15:55:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Jan-15-2021 15:55:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/28/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Date	Location	User	Value	Reason
Jan-15-2021 15:55:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - eCRF Audit Trail History on Dec/28/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Date of Assessment:

Date	Location	User	Value	Reason
Jan-15-2021 15:55:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Jan-15-2021 15:55:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Jan-15-2021 15:55:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Jan-15-2021 15:55:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - 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: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Mar-05-2021 14:07:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	data updated
Mar-05-2021 09:06:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Mar-01-2021 08:36:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly review and complete 'Electronic Sample Tracking - Immunogenicity form' at this visit. Thank you.
Feb-26-2021 10:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Feb/26/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Feb-26-2021 10:49:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: COVID_A1	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled
Visit on Feb/26/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1166**Subject No:** 11661078**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1166) Rapid Medical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Mar-05-2021 09:06:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-05-2021 09:06:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-05-2021 10:35:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-05-2021 09:06:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-05-2021 09:06:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/26/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-05-2021 10:35:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRCX0M	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - 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: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.a Sample ID

Date	Location	User	Value	Reason
Mar-05-2021 10:35:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRCX0M	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-05-2021 10:35:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRCX0N	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-05-2021 10:35:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRCX0N	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-05-2021 10:35:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRCX0P	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-05-2021 10:35:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRCX0P	Initial Entry

5.d

Date	Location	User	Value	Reason
Mar-05-2021 17:23:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Sample ID: BLB05F	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - 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: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.d Sample ID

Date	Location	User	Value	Reason
Mar-05-2021 17:23:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: BLB05F	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Date	Location	User	Value	Reason
Dec-30-2020 10:07:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Dec-30-2020 10:07:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-30-2020 10:07:27 (UTC-05:00) Eastern 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
Feb-17-2021 15:46:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 4: Closed	Response satisfies query
Feb-17-2021 15:46:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 3: Closed	Response satisfies query
Feb-17-2021 15:45:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Closed	Response satisfies query
Feb-17-2021 11:49:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Query 4: Answered	PATIENT NON-RESPONSIVE: SITE PLANS TO SEND LETTER VIA CERTIFIED MAIL(TM) SERVICE THIS WEEK.
Feb-17-2021 11:49:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Query 3: Answered	PREVIOUSLY ENTERED SYMPTOMS AS PART OF A NEW ILLNESS VISIT: PLEASE CLOSE QUERY, PER CRA.

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Feb-17-2021 11:48:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Query 2: Answered	PREVIOUSLY ENTERED SYMPTOMS AS PART OF ILLNESS VISIT: PLEASE CLOSE QUERY, PER CRA.
Jan-17-2021 04:57:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	term updated in SDB.
Jan-08-2021 17:42:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 4: Opened	Clin: Despite telehealth visit was not done, please complete the potential COVID-19 Illness Visit CRF forms with all information available and a NASAL SWAB collected ASAP if the symptom are ongoing or resolved no more than 4d ago
Jan-08-2021 17:39:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 3: Opened	Clin: The symptoms reported in the SAE report #2020518933, should have please triggered a COVID-19 Visit irrespective of perceived etiology or clinical significance and captured only on the CRF SOD form.
Jan-08-2021 17:37:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Opened	Clin: It was stated in the SAE report #2020518933, that the subject experienced fever, nonproductive cough, body aches, chills, diarrhea, fatigue, headache, loss of taste and smell, runny nose, nasal

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1166

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

				congestion, sore throat, nausea, vomiting and diarrhea
Jan-06-2021 06:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	Pending SDB update
Jan-05-2021 12:48:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Query 1: Answered	YES: FU1 was faxed yesterday (MON, 04JAN2021). Confirmation of fax received by us from machine. No further communications received from Pfizer nor ICON. FU1 report amended term to match this EDC.
Jan-05-2021 08:13:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	SAE RECON 1: Please confirm if a follow up AEM form was submitted to also update term in Safety database
Jan-04-2021 07:25:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Query 1: Answered	Term in InForm is correct as-is. Investigator will follow up via SAE fax line to amend entry to match, if needed.
Jan-02-2021 06:15:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2020518933, the term in Safety database was recorded as 'SUBJECT PREGNANT (REPORTS PREGNANCY (+) TEST)' while Exposure during pregnancy in AE CRF.Please submit a follow up AEM form to update term in Safety database.

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Dec-30-2020 10:07:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: EXPOSURE DURING PREG NANCY	Initial Entry
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4. Start Date Time:

Date	Location	User	Value	Reason
Mar-04-2021 07:08:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	thank you for the clarification. Closing query to FU at a later date.
Feb-25-2021 13:28:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject is coming in for in person visit tomorrow, will clarify date of conception given by her OBGYN at tomorrows visit and will update the data at that point. Thanks. FOr now this date is being used as a placeholder as this is the date of 1st + preg tes
Feb-24-2021 15:35:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Opened	I don't think I am following the response. Pls specify what section of the CRF CG states the onset date of EDP should be date of first positive pregnancy test.
Feb-17-2021 11:50:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Query 1: Answered	18-DEC-2020 WAS DATE OF *FIRST* URINE PREGNANCY TEST DONE BY PATIENT (AT-HOME KIT).
Feb-11-2021 02:07:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Pls clarify, why is this the onset date for exposure during pregnancy?

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1166**Subject No:** 11661078**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1166) Rapid Medical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23

Feb-10-2021 13:19:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Candidate	Pls clarify, why is this the onset date for exposure during pregnancy?
Feb-02-2021 16:31:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Query 1: Answered	PATIENT IS NON-RESPONSIVE DESPITE REPEATED FOLLOW-UP ATTEMPTS. UNABLE TO PROVIDE THIS INFORMATION.
Jan-08-2021 17:23:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	CLINICAL_ Based on CRF CG (section 8.50.2.5), when the pregnancy occurred after Vax1, the onset date should be determined by ultrasound or LMP. Please revise and update accordingly. Thanks.
Dec-30-2020 10:07:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Dec/18/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-30-2020 10:07:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-30-2020 10:14:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Not Applicable	Initial Entry
Dec-30-2020 10:14:21 (UTC-05:00) Eastern	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry:	GRADE NOT APPLICABLE PER

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Time (US & Canada)				PROTOCOL (SECTION 8.50.2.5).
Dec-30-2020 10:12:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	<u>Data Entry:</u> 1	Initial Entry
Dec-30-2020 10:08:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	<u>Data Entry:</u>	Transcription Error
Dec-30-2020 10:07:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	<u>Data Entry:</u> 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Jan-05-2021 08:14:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	downgraded to non serious
Jan-04-2021 11:38:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	<u>Data Entry:</u> NO	PER DM/SR CRA, ANSWER IS NO UNLESS/UNTIL PREGNANCY RESULTS IN BIRTH ABNORMALITY. THUS, AMENDING FROM "OTHER = YES" TO "NO" (NOT SERIOUS), PER SR CRA/PROTOCOL AND TO MATCH PFIZER SAFETY DATABASE.
Jan-04-2021 07:29:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Query 2: Answered	Query is ambiguous. Please clarify the specific CRF and specific line item that needs amended. Else, we believe accurate as-is.
Jan-02-2021	ACV0PFEINFP6000	(b) (6)	Query 2: Opened	SAE RECON:

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

06:18:05 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		AER#2020518933,'EXPOSURE DURING PREGNANCY' event was appropriately reported to safety; however, seriousness criteria is met there is an abnormal pregnancy outcome/protocol section 8.3.5.1. Please update seriousness criteria accordingly.
Jan-02-2021 06:17:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally
Dec-30-2020 10:07:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE EXPOSURE DURING PREGNANCY: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-30-2020 10:07:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: YES Is this serious event as sociated with congenit al anomaly or birth de fect? NO Did this serious event result in death? NO Did this serious event require or prolong hos pitalization? NO Did this serious event result in persistent or significant disability/i ncapacity? NO	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

			Is this serious event life threatening?	
			NO	
			Other medically important serious event	
			YES	

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Dec-30-2020 10:07:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-04-2021 09:37:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> EXPOSURE DURING PREGNANCY	PER DM, AMENDED TO MATCH SAE NAME ITSELF (LINE 1 OF THIS CRF) AND TO MATCH SAE NAME AS REPORTED VIA FAX TO PFIZER.
Dec-30-2020 10:07:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> EXPOSURE - POSITIVE PREGNANCY TEST	Initial Entry

10. Latest Action Taken with Study Treatment:

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Date	Location	User	Value	Reason
Dec-30-2020 10:07:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-30-2020 10:07:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-30-2020 10:07:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-05-2021 08:12:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-05-2021 06:47:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Jan-05-2021 00:31:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-04-2021 11:40:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Query 3: Answered	PER CRF GUIDELINES (AND PER SR CRA), OUTCOME IS "UNKNOWN". DO NOT RE-QUERY BECAUSE THIS IS PER CRF GUIDELINES V11.

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-04-2021 11:39:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	For AE EXPOSURE DURING PREGNANCY: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Jan-04-2021 11:39:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: UNKNOWN	PER SR CRA/PER CRF GUIDELINES, AMENDED FROM "NOT RECOVERED/NOT RESOLVED" TO "UNKNOWN" AND TO MATCH SAE F/U AND PFIZER SAFETY DATABASE.
Jan-04-2021 09:39:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: NOT RECOVERED/NOT RE SOLVED	PER DM QUERY/TO MATCH END DATE (NOT YET ENDED). NOT RECOVERED/NOT RESOLVED SINCE BIRTH AS A RESULT OF PREGNANCY HAS NOT YET HAPPENED, THUS "NOT RECOVERED/NOT RESOLVED" IS MORE ACCURATE THAN "UNKNOWN."

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1166**Subject No:** 11661078**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete**Site Name:** (1166) Rapid Medical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23

Jan-04-2021 07:30:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Query 2: Answered	Patient is STILL pregnant, thus SAE is indeed ongoing until birth. Please advise the specific CRF and specific line-item that needs changed. Else, we believe all information is correct as-is.
Jan-04-2021 07:29:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE EXPOSURE DURING PREGNANCY: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Jan-04-2021 07:29:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Per query.
Jan-04-2021 07:29:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: UNKNOWN	Per query.
Jan-02-2021 06:17:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2020518933, the outcome in AE CRF was reported as NOT RECOVERED/NOT RESOLVED. Per 3 Nov EDP guidance (study communication), outcome should be recorded as UNKNOWN. Please confirm and update accordingly.
Dec-30-2020 10:07:27	ACV0PFEINFP6000	Cory Kozlovich	Data Entry:	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

(UTC-05:00) Eastern Time (US & Canada)		(b) (4)	NOT RECOVERED/NOT RE SOLVED
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Dec-30-2020 10:07:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-06-2020 08:45:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Form Deleted	Per eCRF guidelines, non-vaccine medications are NOT reportable for this phase. Removed per CRA instruction.
Oct-06-2020 08:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Form Created	

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Incomplete, Data Complete, Deleted, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

[Back to Form](#)

1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-06-2020 08:44:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Per eCRF guidelines, non-vaccine medications are NOT reportable for this phase. Removed per CRA instruction.
Oct-06-2020 08:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-06-2020 08:44:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Per eCRF guidelines, non-vaccine medications are NOT reportable for this phase. Removed per CRA instruction.
Oct-06-2020 08:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-06-2020 08:44:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Per eCRF guidelines, non-vaccine medications are NOT reportable for this phase. Removed per CRA instruction.
Oct-06-2020 08:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Incomplete, Data Complete, Deleted, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

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-06-2020 08:44:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	<u>Data Entry:</u>	Per eCRF guidelines, non-vaccine medications are NOT reportable for this phase. Removed per CRA instruction.
Oct-06-2020 08:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	<u>Data Entry:</u> LOESTRIN FE 24 hr (Ethinyl e stradiol 0.03 mg & norethindron e acetate 1.5 mg [21 tab] and...)	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Oct-06-2020 08:44:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	<u>Data Entry:</u>	Per eCRF guidelines, non-vaccine medications are NOT reportable for this phase. Removed per CRA instruction.
Oct-06-2020 08:40:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	<u>Data Entry:</u> Sep/1/2020	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Nov-03-2020 09:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Nov/2/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-03-2020 09:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-03-2020 09:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Feb-25-2021 15:08:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/18/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History

Form Status: Data Complete, Frozen

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Feb-25-2021 15:08:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-25-2021 15:08:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/22/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Mar-09-2021 04:40:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Clo sed	Response satisfies query
Mar-08-2021 15:09:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Query 2: An swere d	SUBJECT WAS (ERRONEOUSLY, BY SITE) UNBLINDED VIA FORM 1 INSTEAD OF VIA IMPALA. PLEASE ADVISE, ELSE: CORRECT AS-IS.
Mar-08-2021 01:59:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Op ened	IVRS Reconciliation: Other is selected as the primary reason for unblinding but matching blind break is not captured in IRT. Please correct primary reason in Inform or confirm as correct".
Mar-05-2021 22:04:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Clo sed	Auto closed by Validation Check: VC_DS001_35
Mar-05-2021	ACV0PFEINFP6000	Cory Kozlovich	Query	ORIGINAL VALUE

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

17:25:57 (UTC-05:00) Eastern Time (US & Canada)		(b) (4)	1: Answered	CORRECT AS-IS: SUBJECT WAS "WILLING" TO BE UNBLINDED. PARTICIPANT IS PREGNANT AND THUS INELG. FOR VAX VIA STUDY: SHE STILL WISHED TO BE UNBLINDED AND WAS SO PER SPONSOR'S REQUEST TO UNBLIND *ALL* PARTICIPANTS BY 01MAR2021. DO NOT RE-QUERY.
Mar-05-2021 15:07:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rivkah Rosen (b) (4)	Query 1: Reissued: Opened	DM: Form has been unfrozen. Primary Reason for Unblinding is "ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION", but "Participant is willing to return for Vaccination 3" is not selected in the Further Vaccination Confirmation CRF. Please update.
Mar-05-2021 09:07:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Mar-05-2021 09:07:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : OTHER <i>If other, specify</i>	New Information

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

			<p><i>ify:</i></p> <p>su bj i s S AE su nj an d wil l n ot be abl e t o r ece ive va cc but stil l w ish ed to be un bli nd ed</p>	
Feb-26-2021 17:25:50 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW7478521;Primary Reason for Unblinding is "ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION", but "Participant is willing to return for Vaccination 3" is not selected in the Further Vaccination Confirmation CRF. Please review and update as appropriate.

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Feb-25-2021 15:08:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry : ASSE SS EL IGIBI LITY FOR ADDI TION AL V ACCI NATI ON	Initial Entry
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090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1166

Subject No: 11661078

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1166) Rapid Medical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Nov-03-2020 09:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-16-2020 09:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-16-2020 09:27:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Nov-03-2020 09:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/2/2020	Initial Entry
Sep-16-2020 09:32:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/15/2020	Initial Entry
Sep-16-2020 09:27:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/15/2020	Initial Entry

090177e196ae3d0e\Final\Final On: 01-Apr-2021 04:24 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1166

Site Name: (1166) Rapid Medical Research

Subject No: 11661078

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Nov-11-2020 11:54:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Cory Kozlovich (b) (4)	Data Entry: Click Here to Enable	Initial Entry