

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/4/2020
----	--------------	---------------------------------------------------------

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11071031]
2.	Birth Date:	(b) (6) /1972
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: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/4/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Aug/4/2020
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: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ACID REFLUX]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ANXIETY]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[DEPRESSION]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HAND, SHOULDER AND HIP OSTEOARTHRITIS]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[RIGHT FOOT NEUROMA]
	Start Date:	UNK/UNK/2018
	Ongoing:	NO End Date: UNK/UNK/2018
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[NEUROMA R FOOT SURGERTY]
	Start Date:	UNK/UNK/2018
	Ongoing:	NO End Date: UNK/UNK/2018
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[SEASONAL ALLERGIES]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[BACTRIM ALLERGY]
	Start Date:	UNK/UNK/2011
	Ongoing:	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[IRRITABLE BOWEL SYNDROME]
	Start Date:	UNK/UNK/1989
	Ongoing:	YES
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[RAYNAUD'S PHENOMENON]
	Start Date:	UNK/UNK/2007
	Ongoing:	YES

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/4/2020
2.	Weight:	[161.0]
3.	Unit:	LB
4.	Height:	[64.0]
5.	Unit:	in
6.	Body Mass Index:	[27.6]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.7]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/4/2020
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:	

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/4/2020
2.	Randomization Number:	[42374]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/4/2020
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	[BPLFGZ]
5.b	Sample ID	[BPLFH0]
5.c	Sample ID	[BPLFH1]
5.d	Sample ID	[BP3SCH]
5.e	Sample ID	[BP3SCJ]
5.f	Sample ID	[BP3SCK]

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/4/2020
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	[BP3SBH]
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090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/4/2020 15:22
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

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
----	---------------------------------------------------------------	---------------------------------------------------------

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/31/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/14/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.3]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/14/2020
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:	

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/14/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPYKSC]
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090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	YES Date of First Delay: Aug/31/2020 Reason(s) for Temporary Delay of Vaccination RECENT NON-STUDY VACCINATION
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/14/2020 14:58
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

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/12/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

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

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/12/2020
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	[BPYDYC]
5.b	Sample ID	[BNWX20]
5.c	Sample ID	[BNWX1N]

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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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090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Nov/29/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Date of Visit

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

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
on Nov/29/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Nov/29/2020
2.	Date of First Symptom Started:	Nov/25/2020
3.	Symptoms Ongoing?	NO
	Date of Last Symptom Resolved:	Dec/13/2020

Symptoms

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

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
on Nov/29/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Symptoms - Other

5.a	Symptoms - Other Text:	[ABDOMINAL PAIN]
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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Nov/28/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Nov/29/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Nov/28/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[SUBJECT WAS TESTED AT THE HOSPITAL]
9.	Trade Name Other, Specify:	[SARS COV-2 (COVID-19) PCR CLIA CERTIFIED LAB]

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Nov/29/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Dec/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	[RW85704]
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090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
on Nov/29/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Nov/29/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1107**Site Name:** (1107) Coastal Clinical Research**Subject No:** 11071031**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49[eCRF Audit Trail History](#)**Health Care Utilization**

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

Health Care Utilization Other

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

Health Care Utilization

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: HOSPITALIZATION DETAILS

Form Version: 22-Apr-2020 21:02

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1.	HOSPITALIZATION STATUS	HOSPITAL	Nov/27/2020	NO Discharge Date: Dec/2/2020	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS
on Nov/29/2020

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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[Form Audit Trail](#)

Hospitalization Details

1.	Hospitalization Category:	HOSPITALIZATION STATUS
2.	Hospitalization Term:	HOSPITAL
3.	Admission Date:	Nov/27/2020
4.	Ongoing?	NO Discharge Date: Dec/2/2020

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT
on Nov/29/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Respiratory Treatment

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

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS
on Nov/29/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [COLITIS] Date of Diagnosis: Nov/30/2020
3.	Toxicity Grade:	3

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

#	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

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Nov/29/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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[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: 30-Jul-2020 21:27

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1. DELETED	CLINICAL CHEMISTRY	MOBILE INFIRMARY MEDICAL CLINIC LAB, 5 MOBILE INFIRMARY DRIVE, MOBILE, AL	Nov/28/2020	BLOOD	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					329	Not Applicable		
					30	Not Applicable	18	
					28	Not Applicable	32	
					35	Not Applicable	94	
					21	Not Applicable	0.3	
					47	Not Applicable	10	
					48	Not Applicable	0.73	

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 10-Oct-2020 15:58

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result	Form Instance																								
2.	CLINICAL CHEMISTRY	MOBILE INFIRMARY MEDICAL CLINIC LAB, 5 MOBILE INFIRMARY CIRCLE, MOBILE, AL	Nov/28/2020	BLOOD	<table border="1"> <thead> <tr> <th>Sponsor-Defined Identifier</th> <th>Test:</th> <th>Result:</th> </tr> </thead> <tbody> <tr> <td>329</td> <td>C Reactive Protein_PX329</td> <td>[]</td> </tr> <tr> <td>30</td> <td>Alanine Aminotransferase_PX30</td> <td>11</td> </tr> <tr> <td>28</td> <td>Aspartate Aminotransferase_PX28</td> <td>17</td> </tr> <tr> <td>35</td> <td>Alkaline Phosphatase_PX35</td> <td>73</td> </tr> <tr> <td>21</td> <td>Bilirubin_PX21</td> <td>0.3</td> </tr> <tr> <td>47</td> <td>Blood Urea Nitrogen_PX47</td> <td>11</td> </tr> <tr> <td>48</td> <td>Creatinine_PX48</td> <td>0.81</td> </tr> </tbody> </table>	Sponsor-Defined Identifier	Test:	Result:	329	C Reactive Protein_PX329	[]	30	Alanine Aminotransferase_PX30	11	28	Aspartate Aminotransferase_PX28	17	35	Alkaline Phosphatase_PX35	73	21	Bilirubin_PX21	0.3	47	Blood Urea Nitrogen_PX47	11	48	Creatinine_PX48	0.81	Repeating Pages
					Sponsor-Defined Identifier	Test:	Result:																							
					329	C Reactive Protein_PX329	[]																							
					30	Alanine Aminotransferase_PX30	11																							
					28	Aspartate Aminotransferase_PX28	17																							
					35	Alkaline Phosphatase_PX35	73																							
					21	Bilirubin_PX21	0.3																							
					47	Blood Urea Nitrogen_PX47	11																							
48	Creatinine_PX48	0.81																												
3.	CLINICAL CHEMISTRY	MOBILE INFIRMARY MEDICAL CLINIC LAB, 5 MOBILE INFIRMARY CIRCLE, MOBILE, AL	Nov/29/2020	BLOOD	<table border="1"> <thead> <tr> <th>Sponsor-Defined Identifier</th> <th>Test:</th> <th>Result:</th> </tr> </thead> <tbody> <tr> <td>329</td> <td>C Reactive Protein_PX329</td> <td>[]</td> </tr> <tr> <td>30</td> <td>Alanine Aminotransferase_PX30</td> <td>10</td> </tr> <tr> <td>28</td> <td>Aspartate Aminotransferase_PX28</td> <td>15</td> </tr> <tr> <td>35</td> <td>Alkaline Phosphatase_PX35</td> <td>64</td> </tr> </tbody> </table>	Sponsor-Defined Identifier	Test:	Result:	329	C Reactive Protein_PX329	[]	30	Alanine Aminotransferase_PX30	10	28	Aspartate Aminotransferase_PX28	15	35	Alkaline Phosphatase_PX35	64	Repeating Pages									
					Sponsor-Defined Identifier	Test:	Result:																							
					329	C Reactive Protein_PX329	[]																							
					30	Alanine Aminotransferase_PX30	10																							
					28	Aspartate Aminotransferase_PX28	15																							
					35	Alkaline Phosphatase_PX35	64																							

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 10-Oct-2020 15:58

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
					Sponsor-Defined Identifier	Test:	Result:	
						35		
					21	Bilirubin_PX21	0.2	
					47	Blood Urea Nitrogen_PX47	5	
					48	Creatinine_PX48	0.71	
4.	CLINICAL CHEMISTRY	MOBILE INFIRMARY MEDICAL CLINIC LAB, 5 MOBILE INFIRMARY CIRCLE, MOBILE, AL	Nov/30/2020	BLOOD				Repeating Pages
					329	C Reactive Protein_PX329	[]	
					30	Alanine Aminotransferase_PX30	12	
					28	Aspartate Aminotransferase_PX28	19	
					35	Alkaline Phosphatase_PX35	69	
					21	Bilirubin_PX21	0.2	
					47	Blood Urea Nitrogen_PX47	2	
					48	Creatinine_PX48	0.73	

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Nov/29/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

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- [eCRF Audit Trail History](#)
- [Form Audit Trail](#)

Lab Chemistry Details

1.	Lab Panel:	CLINICAL CHEMISTRY	Comments
2.	Laboratory Name and Address	[MOBILE INFIRMARY MEDICAL CLINIC LAB, 5 MOBILE INFIRMARY DRIVE, MOBILE, AL]	Comments
3.	Collection Date:	Nov/28/2020	Comments
4.	Specimen Type:	BLOOD	Comments

Lab Result

5.a	Sponsor ID:	[329]	Comments
	Test:	C Reactive Protein_PX329	
	Result:	[]	Comments
	Not Done:	NOT DONE	Comments
	LNMT	Low [] High [] Unit	Comments
5.b	Sponsor ID:	[30]	Comments
	Test:	Alanine Aminotransferase_PX30	
	Result:	[48]	Comments
	Not Done:		Comments
	LNMT	Low [0] High [40] Unit U/L	Comments

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Nov/29/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

5.e	Sponsor ID:	[28]	Comments
	Test:	Aspartate Aminotransferase_PX28	
	Result:	[32]	Comments
	Not Done:		Comments
	LNMT	Low [0] High [40] Unit U/L	Comments
5.d	Sponsor ID:	[35]	Comments
	Test:	Alkaline Phosphatase_PX35	
	Result:	[94]	Comments
	Not Done:		Comments
	LNMT	Low [30] High [115] Unit U/L	Comments
5.e	Sponsor ID:	[21]	Comments
	Test:	Bilirubin_PX21	
	Result:	[0.3]	Comments
	Not Done:		Comments
	LNMT	Low [0.2] High [1.2] Unit mg/dL	Comments

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Nov/29/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

5-f	Sponsor ID:	[47]	Comments
	Test:	Blood Urea Nitrogen_PX47	
	Result:	[40]	Comments
	Not Done:		Comments
	LNMT	Low [5] High [25] Unit mg/dL	Comments

5-g	Sponsor ID:	[48]	Comments
	Test:	Creatinine_PX48	
	Result:	[0.73]	Comments
	Not Done:		Comments
	LNMT	Low [0.54] High [0.95] Unit mg/dL	Comments

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Nov/29/2020

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

Lab Chemistry Details

1.	Lab Panel:	CLINICAL CHEMISTRY
2.	Laboratory Name and Address	[MOBILE INFIRMARY MEDICAL CLINIC LAB, 5 MOBILE INFIRMARY CIRCLE, MOBILE, AL]
3.	Collection Date:	Nov/28/2020
4.	Specimen Type:	BLOOD

Lab Result

5.a	Sponsor ID:	[329]
	Test:	C Reactive Protein_PX329
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.b	Sponsor ID:	[30]
	Test:	Alanine Aminotransferase_PX30
	Result:	[11]
	Not Done:	
	LNMT	Low [0] High [40] Unit U/L

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

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Generated Time (GMT): 29-Mar-2021 10:49

5.c	Sponsor ID:	[28]
	Test:	Aspartate Aminotransferase_PX28
	Result:	[17]
	Not Done:	
	LNMT	Low [0] High [40] Unit U/L

5.d	Sponsor ID:	[35]
	Test:	Alkaline Phosphatase_PX35
	Result:	[73]
	Not Done:	
	LNMT	Low [30] High [115] Unit U/L

5.e	Sponsor ID:	[21]
	Test:	Bilirubin_PX21
	Result:	[0.3]
	Not Done:	
	LNMT	Low [0.2] High [1.2] Unit mg/dL

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5.f	Sponsor ID:	[47]
	Test:	Blood Urea Nitrogen_PX47
	Result:	[11]
	Not Done:	
	LNMT	Low [5] High [25] Unit mg/dL

5.g	Sponsor ID:	[48]
	Test:	Creatinine_PX48
	Result:	[0.81]
	Not Done:	
	LNMT	Low [0.51] High [0.95] Unit mg/dL

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Lab Chemistry Details

1.	Lab Panel:	CLINICAL CHEMISTRY
2.	Laboratory Name and Address	[MOBILE INFIRMARY MEDICAL CLINIC LAB, 5 MOBILE INFIRMARY CIRCLE, MOBILE, AL]
3.	Collection Date:	Nov/29/2020
4.	Specimen Type:	BLOOD

Lab Result

5.a	Sponsor ID:	[329]
	Test:	C Reactive Protein_PX329
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.b	Sponsor ID:	[30]
	Test:	Alanine Aminotransferase_PX30
	Result:	[10]
	Not Done:	
	LNMT	Low [0] High [40] Unit U/L

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Generated Time (GMT): 29-Mar-2021 10:49

5.c	Sponsor ID:	[28]
	Test:	Aspartate Aminotransferase_PX28
	Result:	[15]
	Not Done:	
	LNMT	Low [0] High [40] Unit U/L

5.d	Sponsor ID:	[35]
	Test:	Alkaline Phosphatase_PX35
	Result:	[64]
	Not Done:	
	LNMT	Low [30] High [115] Unit U/L

5.e	Sponsor ID:	[21]
	Test:	Bilirubin_PX21
	Result:	[0.2]
	Not Done:	
	LNMT	Low [0.2] High [1.2] Unit mg/dL

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5.f	Sponsor ID:	[47]
	Test:	Blood Urea Nitrogen_PX47
	Result:	[5]
	Not Done:	
	LNMT	Low [5] High [25] Unit mg/dL

5.g	Sponsor ID:	[48]
	Test:	Creatinine_PX48
	Result:	[0.71]
	Not Done:	
	LNMT	Low [0.51] High [0.95] Unit mg/dL

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Lab Chemistry Details

1.	Lab Panel:	CLINICAL CHEMISTRY
2.	Laboratory Name and Address	[MOBILE INFIRMARY MEDICAL CLINIC LAB, 5 MOBILE INFIRMARY CIRCLE, MOBILE, AL]
3.	Collection Date:	Nov/30/2020
4.	Specimen Type:	BLOOD

Lab Result

5.a	Sponsor ID:	[329]
	Test:	C Reactive Protein_PX329
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.b	Sponsor ID:	[30]
	Test:	Alanine Aminotransferase_PX30
	Result:	[12]
	Not Done:	
	LNMT	Low [0] High [40] Unit U/L

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5.c	Sponsor ID:	[28]
	Test:	Aspartate Aminotransferase_PX28
	Result:	[19]
	Not Done:	
	LNMT	Low [0] High [40] Unit U/L

5.d	Sponsor ID:	[35]
	Test:	Alkaline Phosphatase_PX35
	Result:	[69]
	Not Done:	
	LNMT	Low [30] High [115] Unit U/L

5.e	Sponsor ID:	[21]
	Test:	Bilirubin_PX21
	Result:	[0.2]
	Not Done:	
	LNMT	Low [0.2] High [1.2] Unit mg/dL

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Generated Time (GMT): 29-Mar-2021 10:49

5.f	Sponsor ID:	[47]
	Test:	Blood Urea Nitrogen_PX47
	Result:	[2]
	Not Done:	
	LNMT	Low [5] High [25] Unit mg/dL

5.g	Sponsor ID:	[48]
	Test:	Creatinine_PX48
	Result:	[0.73]
	Not Done:	
	LNMT	Low [0.51] High [0.95] Unit mg/dL

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result	Form Instance																																	
1. DELETED	HEMATOLOGY	MOBILE INFIRMARY MEDICAL CLINIC LAB, 5 MOBILE INFIRMARY CIRCLE, MOBILE, AL 36607	Nov/28/2020	BLO OD	<table border="1"> <thead> <tr> <th data-bbox="1058 493 1183 611">Sponsor-Defined Identifier</th> <th data-bbox="1183 493 1265 611">Test:</th> <th data-bbox="1265 493 1330 611">Result:</th> </tr> </thead> <tbody> <tr> <td data-bbox="1058 611 1183 726">1</td> <td data-bbox="1183 611 1265 726">Not Applicable</td> <td data-bbox="1265 611 1330 726">12.0</td> </tr> <tr> <td data-bbox="1058 726 1183 842">2</td> <td data-bbox="1183 726 1265 842">Not Applicable</td> <td data-bbox="1265 726 1330 842">38</td> </tr> <tr> <td data-bbox="1058 842 1183 957">3</td> <td data-bbox="1183 842 1265 957">Not Applicable</td> <td data-bbox="1265 842 1330 957">4.69</td> </tr> <tr> <td data-bbox="1058 957 1183 1073">5</td> <td data-bbox="1183 957 1265 1073">Not Applicable</td> <td data-bbox="1265 957 1330 1073">216</td> </tr> <tr> <td data-bbox="1058 1073 1183 1188">7</td> <td data-bbox="1183 1073 1265 1188">Not Applicable</td> <td data-bbox="1265 1073 1330 1188">10.3</td> </tr> <tr> <td data-bbox="1058 1188 1183 1304">608</td> <td data-bbox="1183 1188 1265 1304">Not Applicable</td> <td data-bbox="1265 1188 1330 1304">7.44</td> </tr> <tr> <td data-bbox="1058 1304 1183 1419">609</td> <td data-bbox="1183 1304 1265 1419">Not Applicable</td> <td data-bbox="1265 1304 1330 1419">0.07</td> </tr> <tr> <td data-bbox="1058 1419 1183 1535">612</td> <td data-bbox="1183 1419 1265 1535">Not Applicable</td> <td data-bbox="1265 1419 1330 1535">1.01</td> </tr> <tr> <td data-bbox="1058 1535 1183 1650">610</td> <td data-bbox="1183 1535 1265 1650">Not Applicable</td> <td data-bbox="1265 1535 1330 1650">0.05</td> </tr> <tr> <td data-bbox="1058 1650 1183 1728">611</td> <td data-bbox="1183 1650 1265 1728">Not Applicable</td> <td data-bbox="1265 1650 1330 1728">1.71</td> </tr> </tbody> </table>	Sponsor-Defined Identifier	Test:	Result:	1	Not Applicable	12.0	2	Not Applicable	38	3	Not Applicable	4.69	5	Not Applicable	216	7	Not Applicable	10.3	608	Not Applicable	7.44	609	Not Applicable	0.07	612	Not Applicable	1.01	610	Not Applicable	0.05	611	Not Applicable	1.71	Repeating Pages
Sponsor-Defined Identifier	Test:	Result:																																					
1	Not Applicable	12.0																																					
2	Not Applicable	38																																					
3	Not Applicable	4.69																																					
5	Not Applicable	216																																					
7	Not Applicable	10.3																																					
608	Not Applicable	7.44																																					
609	Not Applicable	0.07																																					
612	Not Applicable	1.01																																					
610	Not Applicable	0.05																																					
611	Not Applicable	1.71																																					

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 10-Oct-2020 16:02

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

#	Category for Lab Test	Vendor Name (DERIVED)	Collect ion Date:	Speci men T ype	Lab Result	Form Insta nce																																	
2.	HEMATOLOGY	MOBILE INFIRMARY MEDICAL CLINIC LAB, 5 MOBILE INFIRMARY CIRCLE, MOBILE, AL	Nov/28/2020	BLOOD	<table border="1"> <thead> <tr> <th>Sponsor-Defined Identifier</th> <th>Test:</th> <th>Result:</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Hemoglobin_PX1</td> <td>9.8</td> </tr> <tr> <td>2</td> <td>Hematocrit_PX2</td> <td>31</td> </tr> <tr> <td>3</td> <td>Erythrocytes_PX3</td> <td>3.87</td> </tr> <tr> <td>5</td> <td>Platelets_PX5</td> <td>309</td> </tr> <tr> <td>7</td> <td>Leukocytes_PX7</td> <td>9.1</td> </tr> <tr> <td>608</td> <td>Neutrophils_PX608</td> <td>5.52</td> </tr> <tr> <td>609</td> <td>Eosinophils_PX609</td> <td>0.07</td> </tr> <tr> <td>612</td> <td>Monocytes_PX612</td> <td>1.27</td> </tr> <tr> <td>610</td> <td>Basophils_PX610</td> <td>0.04</td> </tr> <tr> <td>611</td> <td>Lymphocytes_PX611</td> <td>2.14</td> </tr> </tbody> </table>	Sponsor-Defined Identifier	Test:	Result:	1	Hemoglobin_PX1	9.8	2	Hematocrit_PX2	31	3	Erythrocytes_PX3	3.87	5	Platelets_PX5	309	7	Leukocytes_PX7	9.1	608	Neutrophils_PX608	5.52	609	Eosinophils_PX609	0.07	612	Monocytes_PX612	1.27	610	Basophils_PX610	0.04	611	Lymphocytes_PX611	2.14	Repeating Pages
Sponsor-Defined Identifier	Test:	Result:																																					
1	Hemoglobin_PX1	9.8																																					
2	Hematocrit_PX2	31																																					
3	Erythrocytes_PX3	3.87																																					
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7	Leukocytes_PX7	9.1																																					
608	Neutrophils_PX608	5.52																																					
609	Eosinophils_PX609	0.07																																					
612	Monocytes_PX612	1.27																																					
610	Basophils_PX610	0.04																																					
611	Lymphocytes_PX611	2.14																																					
3.	HEMATOLOGY	MOBILE INFIRMARY MEDICAL CLINIC LAB,5 MOBILE INFIRMARY CIRCLE, MOBILE, AL	Nov/29/2020	BLOOD	<table border="1"> <thead> <tr> <th>Sponsor-Defined Identifier</th> <th>Test:</th> <th>Result:</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Hemoglobin_PX1</td> <td>9.6</td> </tr> <tr> <td>2</td> <td>Hematocrit_PX2</td> <td>30</td> </tr> </tbody> </table>	Sponsor-Defined Identifier	Test:	Result:	1	Hemoglobin_PX1	9.6	2	Hematocrit_PX2	30	Repeating Pages																								
Sponsor-Defined Identifier	Test:	Result:																																					
1	Hemoglobin_PX1	9.6																																					
2	Hematocrit_PX2	30																																					

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Header Text: c4591001

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Site No: 1107

Site Name: (1107) Coastal Clinical Research

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Generated By: (b) (4)

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#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
					Sponsor-Defined Identifier	Test:	Result:	
					3	Erythrocytes_PX3	3.76	
					5	Platelets_PX5	321	
					7	Leukocytes_PX7	7.4	
					608	Neutrophils_PX608	4.18	
					609	Eosinophils_PX609	0.13	
					612	Monocytes_PX612	1.22	
					610	Basophils_PX610	0.03	
					611	Lymphocytes_PX611	1.84	
4.	HEMATOLOGY	MOBILE INFIRMARY MEDICAL CLINIC LAB, 5 MOBILE INFIRMARY CIRCLE, MOBILE, AL	Nov/30/2020	BLOOD				Repeating Pages
					1	Hemoglobin_PX1	10.0	
					2	Hematocrit_PX2	32	
					3	Erythrocytes_PX3	3.96	
					5	Platelets_	326	

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#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
					Sponsor-Defined Identifier	Test:	Result:	
						PX5		
					7	Leukocytes_PX7	6.4	
					608	Neutrophils_PX608	4.22	
					609	Eosinophils_PX609	0.11	
					612	Monocytes_PX612	0.72	
					610	Basophils_PX610	0.02	
					611	Lymphocytes_PX611	1.24	

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Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

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Laboratory Data Hematology

1.	Lab Panel:	HEMATOLOGY	Comments
2.	Laboratory Name and Address	[MOBILE INFIRMARY MEDICAL CLINIC LAB, 5 MOBILE INFIRMARY CIRCLE, MOBILE, AL 36607]	Comments
3.	Collection Date:	Nov/28/2020	Comments
4.	Specimen Type:	BLOOD	Comments

Lab Result

5.a	Sponsor ID:	[4]	Comments
	Test:	Hemoglobin_PX1	
	Result:	[12.0]	Comments
	Not Done:		Comments
	LNMT	Low [12.0] High [14.0] Unit g/dL	Comments
5.b	Sponsor ID:	[2]	Comments
	Test:	Hematocrit_PX2	
	Result:	[38]	Comments
	Not Done:		Comments
	LNMT	Low [36] High [48] Unit %	Comments

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5.e	Sponsor ID:	[3]	Comments
	Test:	Erythrocytes_PX3	
	Result:	[4.69]	Comments
	Not Done:		Comments
	LNMT	Low [4.20] High [5.40] Unit 10^6/cu mm	Comments
5.d	Sponsor ID:	[5]	Comments
	Test:	Platelets_PX5	
	Result:	[216]	Comments
	Not Done:		Comments
	LNMT	Low [140] High [450] Unit 10^3/uL	Comments
5.e	Sponsor ID:	[7]	Comments
	Test:	Leukocytes_PX7	
	Result:	[10.3]	Comments
	Not Done:		Comments
	LNMT	Low [5.0] High [10.0] Unit 10^3/uL	Comments

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5-f	Sponsor ID:	[608]	Comments
	Test:	Neutrophils_PX608	
	Result:	[7.44]	Comments
	Not Done:		Comments
	LNMT	Low [1.80] High [7.00] Unit	Comments
5-g	Sponsor ID:	[609]	Comments
	Test:	Eosinophils_PX609	
	Result:	[0.07]	Comments
	Not Done:		Comments
	LNMT	Low [0.00] High [0.70] Unit 10^9/L	Comments
5-h	Sponsor ID:	[612]	Comments
	Test:	Monocytes_PX612	
	Result:	[1.01]	Comments
	Not Done:		Comments
	LNMT	Low [0.00] High [0.80] Unit 10^9/L	Comments

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5-i	Sponsor ID:	[610]	Comments
	Test:	Basophils_PX610	
	Result:	[0.05]	Comments
	Not Done:		Comments
	LNMT	Low [0.00] High [0.20] Unit 10^9/L	Comments
5-j	Sponsor ID:	[611]	Comments
	Test:	Lymphocytes_PX611	
	Result:	[1.71]	Comments
	Not Done:		Comments
	LNMT	Low [1.00] High [4.80] Unit 10^9/L	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/29/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Laboratory Data Hematology

1.	Lab Panel:	HEMATOLOGY
2.	Laboratory Name and Address	[MOBILE INFIRMARY MEDICAL CLINIC LAB, 5 MOBILE INFIRMARY CIRCLE, MOBILE, AL]
3.	Collection Date:	Nov/28/2020
4.	Specimen Type:	BLOOD

Lab Result

5.a	Sponsor ID:	[1]
	Test:	Hemoglobin_PX1
	Result:	[9.8]
	Not Done:	
	LNMT	Low [12.0] High [14.0] Unit g/dL
5.b	Sponsor ID:	[2]
	Test:	Hematocrit_PX2
	Result:	[31]
	Not Done:	
	LNMT	Low [36] High [48] Unit %

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Nov/29/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

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5.c	Sponsor ID:	[3]
	Test:	Erythrocytes_PX3
	Result:	[3.87]
	Not Done:	
	LNMT	Low [4.20] High [5.40] Unit 10^6/cu mm

5.d	Sponsor ID:	[5]
	Test:	Platelets_PX5
	Result:	[309]
	Not Done:	
	LNMT	Low [140] High [450] Unit 10^3/uL

5.e	Sponsor ID:	[7]
	Test:	Leukocytes_PX7
	Result:	[9.1]
	Not Done:	
	LNMT	Low [5.0] High [10.0] Unit 10^3/uL

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/29/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.f	Sponsor ID:	[608]
	Test:	Neutrophils_PX608
	Result:	[5.52]
	Not Done:	
	LNMT	Low [1.80] High [7.00] Unit 10^9/L

5.g	Sponsor ID:	[609]
	Test:	Eosinophils_PX609
	Result:	[0.07]
	Not Done:	
	LNMT	Low [0.00] High [0.70] Unit 10^9/L

5.h	Sponsor ID:	[612]
	Test:	Monocytes_PX612
	Result:	[1.27]
	Not Done:	
	LNMT	Low [0.00] High [0.80] Unit 10^9/L

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
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Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

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5.i	Sponsor ID:	[610]
	Test:	Basophils_PX610
	Result:	[0.04]
	Not Done:	
	LNMT	Low [0.00] High [0.20] Unit 10^9/L
5.j	Sponsor ID:	[611]
	Test:	Lymphocytes_PX611
	Result:	[2.14]
	Not Done:	
	LNMT	Low [1.00] High [4.80] Unit 10^9/L

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/29/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

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Laboratory Data Hematology

1.	Lab Panel:	HEMATOLOGY
2.	Laboratory Name and Address	[MOBILE INFIRMARY MEDICAL CLINIC LAB,5 MOBILE INFIRMARY CIRCLE, MOBILE, AL]
3.	Collection Date:	Nov/29/2020
4.	Specimen Type:	BLOOD

Lab Result

5.a	Sponsor ID:	[1]
	Test:	Hemoglobin_PX1
	Result:	[9.6]
	Not Done:	
	LNMT	Low [12.0] High [14.0] Unit g/dL
5.b	Sponsor ID:	[2]
	Test:	Hematocrit_PX2
	Result:	[30]
	Not Done:	
	LNMT	Low [36] High [48] Unit %

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Nov/29/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

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5.c	Sponsor ID:	[3]
	Test:	Erythrocytes_PX3
	Result:	[3.76]
	Not Done:	
	LNMT	Low [4.20] High [5.40] Unit 10^6/cu mm

5.d	Sponsor ID:	[5]
	Test:	Platelets_PX5
	Result:	[321]
	Not Done:	
	LNMT	Low [140] High [450] Unit 10^3/uL

5.e	Sponsor ID:	[7]
	Test:	Leukocytes_PX7
	Result:	[7.4]
	Not Done:	
	LNMT	Low [5.0] High [10.0] Unit 10^3/uL

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Nov/29/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

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5.f	Sponsor ID:	[608]
	Test:	Neutrophils_PX608
	Result:	[4.18]
	Not Done:	
	LNMT	Low [1.80] High [7.00] Unit 10^9/L

5.g	Sponsor ID:	[609]
	Test:	Eosinophils_PX609
	Result:	[0.13]
	Not Done:	
	LNMT	Low [0.00] High [0.70] Unit 10^9/L

5.h	Sponsor ID:	[612]
	Test:	Monocytes_PX612
	Result:	[1.22]
	Not Done:	
	LNMT	Low [0.00] High [0.80] Unit 10^9/L

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/29/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

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5.i	Sponsor ID:	[610]
	Test:	Basophils_PX610
	Result:	[0.03]
	Not Done:	
	LNMT	Low [0.00] High [0.20] Unit 10^9/L

5.j	Sponsor ID:	[611]
	Test:	Lymphocytes_PX611
	Result:	[1.84]
	Not Done:	
	LNMT	Low [1.00] High [4.80] Unit 10^9/L

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/29/2020

Form Version: 10-Oct-2020 16:02

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Site No: 1107

Site Name: (1107) Coastal Clinical Research

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Laboratory Data Hematology

1.	Lab Panel:	HEMATOLOGY
2.	Laboratory Name and Address	[MOBILE INFIRMARY MEDICAL CLINIC LAB, 5 MOBILE INFIRMARY CIRCLE, MOBILE, AL]
3.	Collection Date:	Nov/30/2020
4.	Specimen Type:	BLOOD

Lab Result

5.a	Sponsor ID:	[1]
	Test:	Hemoglobin_PX1
	Result:	[10.0]
	Not Done:	
	LNMT	Low [12.0] High [14.0] Unit g/dL
5.b	Sponsor ID:	[2]
	Test:	Hematocrit_PX2
	Result:	[32]
	Not Done:	
	LNMT	Low [36] High [48] Unit %

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/29/2020

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Site No: 1107

Site Name: (1107) Coastal Clinical Research

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Subject Initials: ---

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5.c	Sponsor ID:	[3]
	Test:	Erythrocytes_PX3
	Result:	[3.96]
	Not Done:	
	LNMT	Low [4.20] High [5.40] Unit 10^6/cu mm

5.d	Sponsor ID:	[5]
	Test:	Platelets_PX5
	Result:	[326]
	Not Done:	
	LNMT	Low [140] High [450] Unit 10^3/uL

5.e	Sponsor ID:	[7]
	Test:	Leukocytes_PX7
	Result:	[6.4]
	Not Done:	
	LNMT	Low [5.0] High [10.0] Unit 10^3/uL

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Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
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Form Status: Data Complete, Frozen, Verified

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Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

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5.f	Sponsor ID:	[608]
	Test:	Neutrophils_PX608
	Result:	[4.22]
	Not Done:	
	LNMT	Low [1.80] High [7.00] Unit 10^9/L

5.g	Sponsor ID:	[609]
	Test:	Eosinophils_PX609
	Result:	[0.11]
	Not Done:	
	LNMT	Low [0.00] High [0.70] Unit

5.h	Sponsor ID:	[612]
	Test:	Monocytes_PX612
	Result:	[0.72]
	Not Done:	
	LNMT	Low [0.00] High [0.80] Unit 10^9/L

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Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
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Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

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5.i	Sponsor ID:	[610]
	Test:	Basophils_PX610
	Result:	[0.02]
	Not Done:	
	LNMT	Low [0.00] High [0.20] Unit 10^9/L

5.j	Sponsor ID:	[611]
	Test:	Lymphocytes_PX611
	Result:	[1.24]
	Not Done:	
	LNMT	Low [1.00] High [4.80] Unit 10^9/L

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 30-Jul-2020 21:27

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

#	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 Nov/29/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

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Vital Signs

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

Vital Signs Details

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

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 30-Jul-2020 21:28

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

#	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 Nov/29/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Vital Signs

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

Vital Signs Details

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

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

#	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 Nov/29/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Oxygenation Parameters

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

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

#	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 Nov/29/2020

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

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Concomitant Medications

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

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Nov/30/2020	OTHER <i>If other, specify:</i> ABDOMEN/ PELVIS	CT SCAN	ABNORMAL <i>If abnormal, specify findings:</i> INFLAMMATORY CHANGES IN THE RIGHT COLON CONSISTENT WITH COLITIS	Repeating Pages

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING
on Nov/29/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

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Imaging			
1.	Date of Assessment:	Nov/30/2020	Comments
2.	Location of Assessment:	OTHER If other, specify: [ABDOMEN/PELVIS]	Comments
3.	Type of Imaging Exam:	CT SCAN	Comments
4.	Assessment:	ABNORMAL If abnormal, specify findings: [INFLAMMATORY CHANGES IN THE RIGHT COLON CONSISTENT WITH COLITIS]	Comments

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Jan/04/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Date of Visit

1.	Date of Visit	Jan/4/2021
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 Jan/04/2021

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/4/2021
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	[BNWX9F]
5.b	Sample ID	[BNWX9S]
5.c	Sample ID	[BPYF3F]

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Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Unplanned Assessments

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

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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: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/12/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

Disposition - Follow-Up

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	ASCENDING COLITIS	Nov/25/2020 UNK: UNK	NO End Date Time: Dec/13/2020 UNK:UNK	Repeating Pages

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[ASCENDING COLITIS]
4.	Start Date Time:	Nov/25/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/13/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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: [UNKNOWN]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020503632]

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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Medication Error

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

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	INFLUENZA VACCINE	Aug/20/2020	Repeating Pages

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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[Form Audit Trail](#)

Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
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).	[INFLUENZA VACCINE]
5.	Date:	Aug/20/2020

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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Concomitant Medications

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

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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:	

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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?	

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (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: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/7/2021
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: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2
----	-----------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/7/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/12/2020

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: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Harry Studdard	Approved	Mar-12-2021 10:25:33 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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Item	Date	User	Comment
Form	Aug-04-2020 16:41:19 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Nov/29/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Item	Date	User	Comment
Form	Nov-30-2020 13:31:15 (UTC-06:00) Central Time (US & Canada)	(b)(4, (b)(6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Nov/29/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Item	Date	User	Comment
1	Nov-30-2020 13:31:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Nov/29/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Item	Date	User	Comment
2	Nov-30-2020 13:31:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Nov/29/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Item	Date	User	Comment
3	Nov-30-2020 13:31:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Nov/29/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

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4	Nov-30-2020 13:31:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Nov/29/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

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Subject Initials: ---

Generated By: (b) (4)

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Nov/29/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1107

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6	Nov-30-2020 13:31:15 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
on Nov/29/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1107

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Form	Nov-30-2020 13:32:01 (UTC-06:00) Central Time (US & Canada)	(b)(4, (b)(6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
on Nov/29/2020

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1	Nov-30-2020 13:32:01 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Deleted, Frozen

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5.c	Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
5.c	Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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5.d	Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
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Subject Initials: ---

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Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Item	Date	User	Comment
3	Nov-30-2020 13:33:33 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Item	Date	User	Comment
Form	Nov-30-2020 13:33:52 (UTC-06:00) Central Time (US & Canada)	(b)(4, (b)(6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Item	Date	User	Comment
1	Nov-30-2020 13:33:52 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Item	Date	User	Comment
2	Nov-30-2020 13:33:52 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Item	Date	User	Comment
3	Nov-30-2020 13:33:52 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Item	Date	User	Comment
4	Nov-30-2020 13:33:52 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Item	Date	User	Comment
5	Nov-30-2020 13:33:52 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Item	Date	User	Comment
6	Nov-30-2020 13:33:52 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Nov/29/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Item	Date	User	Comment
Form	Dec-02-2020 10:50:28 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
Form	Nov-30-2020 13:34:11 (UTC-06:00) Central Time (US & Canada)	(b)(4, (b)(6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Nov/29/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Item	Date	User	Comment
1	Dec-02-2020 10:50:28 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
1	Nov-30-2020 13:34:11 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

(

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Nov/29/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Item	Date	User	Comment
2	Dec-02-2020 10:50:28 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
2	Nov-30-2020 13:34:11 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Nov/29/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Item	Date	User	Comment
3	Dec-02-2020 10:50:28 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
3	Nov-30-2020 13:34:11 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Nov/29/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Item	Date	User	Comment
4	Dec-02-2020 10:50:28 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	
4	Nov-30-2020 13:34:11 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Harry Studdard	Approved	Mar-12-2021 10:25:33 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

(b) (6)	N/A	Feb-19-2021 14:46:06 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Harry Studdard	Approved	Jan-20-2021 16:23:47 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

(b)(6)	N/A	Nov-30-2020 13:24:00 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (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: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Harry Studdard	Approved	Oct-21-2020 15:51:33 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

(b)(6)	N/A	Oct-07-2020 13:20:19 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Harry Studdard	Approved	Sep-22-2020 10:39:29 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, HarryStuddard, 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	Sep-14-2020 15:44:44 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Harry Studdard	Approved	Sep-09-2020 15:57:52 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (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: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Affidavit:

By my dated signature below, I, HarryStuddard, 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.

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-04-2020 16:39:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 16:39:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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I. Consent Was:

Date	Location	User	Value	Reason
Aug-04-2020 16:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Aug/4/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Subject ID

Date	Location	User	Value	Reason
Aug-04-2020 16:39:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11071031	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-04-2020 16:39:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) /1972	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-04-2020 16:39:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-04-2020 16:39:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 16:39:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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I. Date of Visit

Date	Location	User	Value	Reason
Sep-09-2020 02:56:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Query 1: Closed	related query present on V2
Sep-08-2020 07:02:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Query 1: Answered	kept query on V2
Sep-03-2020 04:04:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Query 1: Reissued:Opened	DM1: Thank you for the information. Kindly respond to the query once the subject has come for the visit on 14Sep20. Thanks.
Sep-02-2020 10:21:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SUBJECT MET DELAY CRITERIA AND WILL NOT BE COMING IN UNTIL 14SEP2020
Sep-02-2020 05:11:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Visit 'V2VX2L' details are expected but missing. Kindly consider to update or else clarify. Thank you.
Aug-04-2020 16:40:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/4/2020	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-04-2020 16:40:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/4/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-04-2020 16:40:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-04-2020 16:40:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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I.a

Date	Location	User	Value	Reason
Aug-04-2020 16:41:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: ACID REFL UX Start Date: UNK/UNK/2 014 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-04-2020 16:41:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 16:41:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ACID REFLUX	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 16:41:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2014	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 16:41:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.b

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

Date	Location	User	Value	Reason
Aug-04-2020 16:41:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: ANXIETY Start Date: UNK/UNK/2014 Ongoing: YES	Initial Entry

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-04-2020 16:41:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 16:41:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ANXIETY	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 16:41:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2014	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 16:41:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Aug-04-2020 16:42:12 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

Time (US & Canada)			Medical History Term: DEPRESSION Start Date: UNK/UNK/2014 Ongoing: YES
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I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-04-2020 16:42:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 16:42:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DEPRESSION	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 16:42:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2014	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 16:42:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Jan-08-2021 08:19:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 4	New Information

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

			Medical History Term: HAND, SHOULDER AND HIP OSTEOARTHRITIS Start Date: UNK/UNK/2017 Ongoing: YES	
Aug-04-2020 16:42:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: SHOULDER AND HIP OSTEOARTHRITIS Start Date: UNK/UNK/2017 Ongoing: YES	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

I.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-04-2020 16:42:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Jan-08-2021 08:19:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HAND, SHOULDER AND HIP OSTEOARTHRITIS	New Information
Aug-04-2020 16:42:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SHOULDER AND HIP OSTEO ARTHRITIS	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 16:42:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2017	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 16:42:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Aug-04-2020 16:43:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 5 ber: Medical Histo RIGHT FOOT NE ry Term: UROMA Start Date: UNK/UNK/2018	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

			Ongoing: NO End Date: UNK/UNK/2018	
--	--	--	----------------------------------------------	--

I.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-04-2020 16:43:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 16:43:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RIGHT FOOT NEUROMA	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 16:43:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/2018	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 16:43:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date: UNK/UNK/2018	Initial Entry

I.f

Date	Location	User	Value	Reason
Aug-04-2020 16:43:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Nu mber: 6	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

			Medical Hist NEUROMA R FOO ory Term: T SURGERTY Start Date: UNK/UNK/2018 Ongoing: NO End Date: UNK/UNK/2018	
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1.f Line/MH Number:

Date	Location	User	Value	Reason
Aug-04-2020 16:43:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 16:43:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEUROMA R FOOT SURGERT Y	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 16:43:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 16:43:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2018	Initial Entry

1.g

Date	Location	User	Value	Reason
Aug-04-2020 16:43:59 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 7	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

Time (US & Canada)			ber: Medical Histor y Term: Start Date: Ongoing:	SEASONAL AL LERGIES UNK/UNK/2018 YES
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I.g Line/MH Number:

Date	Location	User	Value	Reason
Aug-04-2020 16:43:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 7	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 16:43:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> SEASONAL ALLERGIES	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 16:43:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/2018	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 16:43:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

I.h

Date	Location	User	Value	Reason
Aug-04-2020 16:44:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Numb er: Medical History Term:	Initial Entry
			BACTRIM ALL ERGY	

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

			Start Date: UNK/UNK/2011	
			Ongoing: YES	

1.h Line/MH Number:

Date	Location	User	Value	Reason
Aug-04-2020 16:44:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 16:44:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BACTRIM ALLERGY	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Aug-04-2020 16:44:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2011	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Aug-04-2020 16:44:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.i

Date	Location	User	Value	Reason
Dec-18-2020 09:54:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 9 Medical History Term: IRRITABLE BOWEL SYNDROME Start Date: UNK/UNK/1989 Ongoing: YES	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

1.i Line/MH Number:

Date	Location	User	Value	Reason
Dec-18-2020 09:54:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Dec-18-2020 09:54:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: IRRITABLE BOWEL SYNDRO ME	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Dec-18-2020 09:54:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1989	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Dec-18-2020 09:54:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.j

Date	Location	User	Value	Reason
Dec-18-2020 09:55:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 10 mber: Medical Histo RAYNAUD'S PHE ry Term: NOMENON Start Date: UNK/UNK/2007 Ongoing: YES	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

1.j Line/MH Number:

Date	Location	User	Value	Reason
Dec-18-2020 09:55:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

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

Date	Location	User	Value	Reason
Dec-18-2020 09:55:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RAYNAUD'S PHENOMENON	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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<i>1.j Start Date:</i>				
Date	Location	User	Value	Reason
Dec-18-2020 09:55:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2007	Initial Entry

<i>1.j Ongoing:</i>				
Date	Location	User	Value	Reason
Dec-18-2020 09:55:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Date:

Date	Location	User	Value	Reason
Aug-04-2020 16:44:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/4/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-04-2020 16:44:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 161.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-04-2020 16:44:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-04-2020 16:44:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 64.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-04-2020 16:44:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-04-2020 16:44:42 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 27.6	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

Time (US & Canada)

7.a

Date	Location	User	Value	Reason
Aug-04-2020 16:44:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier: 1 : Temperature: 98.7 Temperature Unit F : Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-04-2020 16:44:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-04-2020 16:44:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.7	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-04-2020 16:44:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-04-2020 16:44:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Lab Panel:

Date	Location	User	Value	Reason
Aug-04-2020 16:45:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-04-2020 16:45:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-04-2020 16:45:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/4/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-04-2020 16:45:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-04-2020 16:45:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-04-2020 16:45:08	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

(UTC-06:00) Central Time (US & Canada)		(autocalc)	Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin in Beta_PX113 Result:: NEGATIVE Not Done::
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-04-2020 16:45:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-04-2020 16:45:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-04-2020 16:45:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-04-2020 16:45:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/4/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-04-2020 16:45:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 42374	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (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: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Data Origin

Date	Location	User	Value	Reason
Aug-04-2020 16:45:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-04-2020 16:45:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-05-2020 06:38:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-04-2020 16:45:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-04-2020 16:45:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/4/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-05-2020 06:38:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BPLFGZ	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (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: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.a Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 06:38:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> BPLFGZ	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-05-2020 06:38:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> Sample ID: BPLFH0	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 06:38:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> BPLFH0	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-05-2020 06:38:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> Sample ID: BPLFH1	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 06:38:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> BPLFH1	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-05-2020 06:38:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> Sample ID: BP3SCH	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (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

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Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.d Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 06:38:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> BP3SCH	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-05-2020 06:38:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> Sample ID: BP3SCJ	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 06:38:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> BP3SCJ	Initial Entry

5.f

Date	Location	User	Value	Reason
Aug-05-2020 06:40:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> Sample ID: BP3SCK	Initial Entry

5.f Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 06:40:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> BP3SCK	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (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: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Data Origin

Date	Location	User	Value	Reason
Aug-04-2020 16:45:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-04-2020 16:45:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-05-2020 06:37:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-04-2020 16:45:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-04-2020 16:45:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/4/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-05-2020 06:37:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BP3SBH	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (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: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.a Sample ID

Date	Location	User	Value	Reason
Aug-05-2020 06:37:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: BP3SBH	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-04-2020 16:46:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-04-2020 16:46:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-04-2020 16:46:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-04-2020 16:46:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/4/2020 15:22	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-04-2020 16:46:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-04-2020 16:46:01 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

Time (US & Canada)

7. Route:

Date	Location	User	Value	Reason
Aug-04-2020 16:46:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-04-2020 16:46:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-04-2020 16:46:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-04-2020 16:46:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES - REACTOGENICITY E-DI ARY COLLECTED FOR THIS S UBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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I. Date of Visit

Date	Location	User	Value	Reason
Sep-15-2020 15:44:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-15-2020 05:20:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Query 2: Closed	Response satisfies query
Sep-14-2020 15:47:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Query 2: Answered	UPDATED
Sep-14-2020 15:46:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Query 1: Answered	UPDATED
Sep-11-2020 02:53:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	PDQ RQ1: Thank you for the response, please keep the query open until the data available and update as per previous query response.
Sep-10-2020 13:20:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Query 1: Answered	SUBJECT CAME IN ON 31AUG2020 AND WAS FOUND TO HAVE MET DELAY CRITERIA. WILL RETURN 14SEP2020 TO COMPLETE VISIT.
Sep-09-2020 03:00:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Query 2: Reissued:Opened	DM: Thank you for the response. Please update vaccination details and rest of the visit pages on 14SEP2020 once performed and then forward the query to DM.

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

Sep-08-2020 07:02:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2: Answered	Thank you for the information. Kindly respond to the query once the subject has come for the visit on 14Sep20. Thanks. ACV0PFEINFP6000 2/Sep/2020 10:21:17 (UTC-06:00) pfe.dbekurs Answered SUBJECT MET DELAY CRITERIA AND WILL NOT BE COMING IN UNTIL 14S
Sep-04-2020 03:53:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: Please complete missing (SWAB PFE, VACCINATION, PREGNANCY TEST) forms at this visit. Thanks
Sep-03-2020 04:33:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	PDQ: Date of visit at this visit is out of window (4 day) from Date of visit (04/Aug/2020) at V1D1VX1L visit. Please reconcile and update accordingly, else confirm date is correct as is.
Sep-02-2020 07:27:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Aug/31/2020	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Symptom:: FE VE R Were fever or systemic sy N mptoms present on the las O t day the Subject Diary wa s completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Symptom:: FA TI	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			GU E Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	NO
--	--	--	------------------------------------------------------------------------------------------------------	----

2.b Symptom:

Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

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Subject Initials: ---

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2.c Symptom:

Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> Symptom:: CH IL LS Were fever or systemic sy mptoms present on the las t day the Subject Diary w as completed?: NO	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> NO	Initial Entry

2.e

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

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Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic s ymptoms present on the l ast day the Subject Diary was completed?: NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic sy NO mptoms present on the la st day the Subject Diary was completed?:	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

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Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

2.f Symptom:

Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> Symptom:: NEW OR WORSE NED MU SCLE PA IN Were fever or syste mic symptoms prese nt on the last day th e Subject Diary was completed?: NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> NEW OR WORSE NED MUSC LE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

2.h

Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Symptom:: NEW O R WORS ENED J OINT PA IN Were fever or syste mic symptoms prese nt on the last day th e Subject Diary was completed?: NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: NEW OR WORSENERD JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: LEFT	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.a

Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reacti NO ons present on the last da y the Subject Diary was c ompleted?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Injection Site Reaction:: SW ELL ING Were injection site reacti NO ons present on the last d ay the Subject Diary was completed?:	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-02-2020 07:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: NO	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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I. Date:

Date	Location	User	Value	Reason
Oct-12-2020 04:02:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Luke Cunliffe (b) (4)	Query 1: Closed	Response satisfies query.
Oct-08-2020 00:26:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Per site response
Oct-07-2020 13:22:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Query 2: Answered	DATA CORRECT AS IS. SUBJECT MET TEMPORARY DELAY CRITERIA ON 31AUG2020. RETURNED ON 14SEP2020 TO COMPLETE VISIT DUE TO DELAY CRITERIA.
Oct-07-2020 13:20:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Vital signs Date 14/Sep/2020 is not same as Date of Visit 31/Aug/2020. Please review and update as appropriate or clarify.
Oct-07-2020 13:20:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-07-2020 13:20:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Sep/14/2020	Transcription Error
Oct-07-2020 12:50:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Luke Cunliffe (b) (4)	Query 1: Opened	ClinQuery: Pre-vaccination procedures (vital signs, nasal swabs and pregnancy tests)

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

				must be conducted on the same day as vaccination. Vital signs collection date does not equal vaccination date. Please review/update, or confirm data correct as-is.
Sep-02-2020 07:28:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Aug/31/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-07-2020 13:20:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Record Identifier 1 :: Temperature: 98.3 Temperature Unit: Temperature Location: ORAL CAVITY	Transcription Error
Sep-02-2020 07:28:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Record Identifier 1 :: Temperature: 98.6 Temperature Unit: Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-02-2020 07:28:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: 1	Initial Entry

2.a Temperature:

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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

Date	Location	User	Value	Reason
Oct-07-2020 13:20:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: 98.3	Transcription Error
Sep-02-2020 07:28:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: 98.6	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-02-2020 07:28:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-02-2020 07:28:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: ORAL CAVITY	Initial Entry

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Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-14-2020 15:44:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-14-2020 15:44:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-15-2020 05:14:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Query 1: Closed	temporary delay
Sep-14-2020 15:46:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Query 1: Answered	Original value is correct
Sep-14-2020 15:44:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Collection Date 14/Sep/2020 is not the same as the Date of Visit 31/Aug/2020. Please correct or confirm.
Sep-14-2020 15:44:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Sep/14/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-14-2020 15:44:44	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

(UTC-06:00) Central Time (US & Canada)		(autocalc)	STUDY SITE	
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5. Specimen Type:

Date	Location	User	Value	Reason
Sep-14-2020 15:44:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-14-2020 15:44:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-14-2020 15:44:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-14-2020 15:44:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-14-2020 15:44:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: NEGATIVE	Initial Entry

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Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Data Origin

Date	Location	User	Value	Reason
Sep-14-2020 15:46:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-14-2020 15:46:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-15-2020 05:14:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Query 1: Closed	temporary delay
Sep-14-2020 15:46:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Query 1: Answered	Original value is correct
Sep-14-2020 15:46:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Sep-14-2020 15:46:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-14-2020 15:46:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of Collection 14/Sep/2020 is greater than Date of Visit 31/Aug/2020. Please review and update as

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (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: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

				appropriate, else clarify.
Sep-14-2020 15:46:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: YES Date of Collection: Sep/14/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-14-2020 15:46:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Sample ID: BPYKSC	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-14-2020 15:46:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: BPYKSC	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 22-Apr-2020 21:04**Site No:** 1107**Subject No:** 11071031**Generated By:** (b) (4)**Form:** VACCINATION - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1107) Coastal Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:49[Back to Form](#)**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-20-2020 17:45:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-17-2020 12:12:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Query 1: Answered	Changed data per query
Sep-16-2020 18:42:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: Subject met TDV criteria due to concomitant non-study vax, however, nothing is listed in the con vax log. Please review and update as appropriate. Thanks
Sep-14-2020 15:45:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: YES Date of First Delay: Aug/31/2020 Reason(s) for Temporary Dela y of Vaccination RECENT NON-STUDY VA CCINATION	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-14-2020 15:45:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

Sep-14-2020 15:45:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry
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4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-15-2020 05:15:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Query 1: Closed	temporary delay
Sep-14-2020 15:45:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Query 1: Answered	DELAY CRITERIA MET
Sep-14-2020 15:45:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Dose Date is not equal to Date of Visit 31/Aug/2020 of the corresponding Visit. Please review and update as appropriate.
Sep-14-2020 15:45:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Sep/14/2020 14:58	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-14-2020 15:45:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-14-2020 15:45:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-14-2020 15:45:14	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

(UTC-06:00) Central Time (US & Canada)		(autocalc)	INTRAMUSCULAR	
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10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-14-2020 15:45:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION 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-14-2020 15:45:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-16-2020 00:55:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Query 1: Closed	As per site confirmation - updated PD tracker
Oct-15-2020 09:43:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Query 1: Answered	Subject visit performed 5 days out of window due to being out of town. PD reported to IRB.
Oct-14-2020 07:46:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Query 1: Opened	PDQ: DOV at this visit is out of window (7 day) from DOV (31/Aug /2020) at V2_VAX2_L. Please reconcile and update accordingly, else confirm date is correct as is.
Oct-12-2020 13:46:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Oct/12/2020	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Symptom:: FE VE R Were fever or systemic symptoms present on the last day the Subject Diary was completed?: N O	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Symptom:: FA TI	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			GU E Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	NO
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2.b Symptom:

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

2.c Symptom:

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> Symptom:: CH IL LS Were fever or systemic sy NO mptoms present on the las t day the Subject Diary w as completed?:	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> NO	Initial Entry

2.e

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Symptom:: VO MIT ING Were fever or systemic s ymptoms present on the l ast day the Subject Diary was completed?: NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic sy mptoms present on the la st day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

2.f Symptom:

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> Symptom:: NEW OR WORSE NED MU SCLE PA IN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> NEW OR WORSE NED MUSCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

2.h

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptom:: NEW OR WORSE ENED JOINT PAIN Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NEW OR WORSE ENED JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: LEFT	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.a

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reacti NO ons present on the last da y the Subject Diary was c ompleted?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Injection Site Reaction:: SW ELL ING Were injection site reacti NO ons present on the last d ay the Subject Diary was completed?:	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Injection Site Reaction: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-12-2020 13:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: NO	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (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: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Data Origin

Date	Location	User	Value	Reason
Oct-13-2020 07:59:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-13-2020 07:59:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-13-2020 07:59:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-13-2020 07:59:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-13-2020 07:59:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: YES Date of Collection: Oct/12/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-13-2020 07:59:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Sample ID: BPYDYC	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (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: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.a Sample ID

Date	Location	User	Value	Reason
Oct-13-2020 07:59:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> BPYDYC	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-13-2020 07:59:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> Sample ID: BNWX20	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-13-2020 07:59:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> BNWX20	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-13-2020 07:59:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> Sample ID: BNWX1N	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-13-2020 07:59:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> BNWX1N	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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I. Date of Visit

Date	Location	User	Value	Reason
Dec-04-2020 02:14:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Query 1: Closed	Response satisfies query
Dec-03-2020 14:16:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query
Dec-03-2020 06:43:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Query 1: Reissued:Opened	DM:Thanks for the response, however self swab details are not entered yet, kindly confirm the self swab is done by the subject.
Dec-01-2020 22:59:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Query 1: Reissued:Candidate	Please review this query once data is entered on self swab.
Dec-01-2020 16:22:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject is currently hospitalized and will have her visitor bring the swab from home when they can so that she can self swab.
Dec-01-2020 08:38:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	invalid query
Dec-01-2020 08:37:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM: Kindly review and complete 'Hospitalization details form' at this visit. Thank you.
Dec-01-2020 02:53:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Query 1: Opened	Date of Visit is completed but Date of Collection in both

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Nov/29/2020**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1107**Site Name:** (1107) Coastal Clinical Research**Subject No:** 11071031**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49

				Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Nov-30-2020 13:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Nov-30-2020 13:23:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Nov-30-2020 13:23:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Nov-30-2020 13:23:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Nov/29/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Nov-30-2020 13:23:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Date of Assessment:

Date	Location	User	Value	Reason
Nov-30-2020 13:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Nov/29/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Nov-30-2020 13:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Nov/25/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Dec-14-2020 13:46:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: NO Date of Last Symptom Resolved: Dec/13/2020	New Information
Nov-30-2020 13:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Nov-30-2020 13:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Symptoms: FEVER Symptom Present: YES	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Nov-30-2020 13:24:45 (UTC-06:00) Central	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: FEVER	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Time (US & Canada)	(b) (4), (b) (6)
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4.a Was symptom present?

Date	Location	User	Value	Reason
Nov-30-2020 13:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES	Initial Entry

4.b

Date	Location	User	Value	Reason
Nov-30-2020 13:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptoms NEW OR INCREA : SED COUGH Symptom NO Present:	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Nov-30-2020 13:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Nov-30-2020 13:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Nov-30-2020 13:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptoms: NEW OR INCREASE D SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

4.c Symptoms:

Date	Location	User	Value	Reason
Nov-30-2020 13:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Nov-30-2020 13:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Nov-30-2020 13:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Nov-30-2020 13:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Nov-30-2020 13:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Nov-30-2020 13:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptom NEW OR INCREASED MUSCLE PAIN	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Symptom NO Present:	
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4.e Symptoms:

Date	Location	User	Value	Reason
Nov-30-2020 13:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Nov-30-2020 13:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Nov-30-2020 13:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Symptoms NEW LOSS OF TASTE OR SMELL Symptom NO Present:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Nov-30-2020 13:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Nov-30-2020 13:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

4.g

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090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Date	Location	User	Value	Reason
Nov-30-2020 13:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Symptom NEW OR INCREASED SORE THROAT Symptom NO Present:	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Nov-30-2020 13:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Nov-30-2020 13:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Nov-30-2020 13:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Symptoms: DIARRHEA Symptom Present YES	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1107**Subject No:** 11071031**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1107) Coastal Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:49**4.h Symptoms:**

Date	Location	User	Value	Reason
Nov-30-2020 13:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Nov-30-2020 13:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: YES	Initial Entry

4.i

Date	Location	User	Value	Reason
Nov-30-2020 13:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Symptoms: VOMITIN G Symptom Present NO :	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Nov-30-2020 13:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Nov-30-2020 13:24:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-02-2020 16:09:42 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Time (US & Canada)			Symptoms - Other: ABDOMINAL PAIN	
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5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Dec-02-2020 16:09:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ABDOMINAL PAIN	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail
on Nov/29/2020

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Date	Location	User	Value	Reason
Dec-01-2020 16:27:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Nov/29/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Dec-01-2020 16:27:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/28/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Dec-01-2020 16:27:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWABBED MATERIAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Dec-01-2020 16:27:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Dec-01-2020 16:27:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDRO ME CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Dec-01-2020 16:27:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TES T	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Dec-01-2020 16:27:26 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Nov/29/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Time (US & Canada)				
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7. Test Result:

Date	Location	User	Value	Reason
Dec-01-2020 16:27:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Dec-01-2020 16:27:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SUBJECT WAS TESTED AT THE HOSPITAL	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Dec-01-2020 16:27:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SARS COV-2 (COVID-19) PCR CLIA CERTIFIED LAB	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit
on Nov/29/2020**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF -
eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1107**Site Name:** (1107) Coastal Clinical Research**Subject No:** 11071031**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-03-2020 14:16:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-03-2020 14:16:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-03-2020 14:16:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-03-2020 14:16:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-03-2020 14:16:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: YES Date of Collection: Dec/2/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-03-2020 14:16:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Sample ID: RW85704	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.a Sample ID

Date	Location	User	Value	Reason
Dec-03-2020 14:16:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: RW85704	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

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1. Data Origin

Date	Location	User	Value	Reason
Nov-30-2020 13:30:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-30-2020 13:30:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-30-2020 13:30:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Nov-30-2020 13:30:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: SELF SWAB	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/29/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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I.a

Date	Location	User	Value	Reason
Nov-30-2020 13:30:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-30-2020 13:30:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-30-2020 13:30:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Nov-30-2020 13:30:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/29/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

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1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-30-2020 13:30:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-30-2020 13:30:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

1.c

Date	Location	User	Value	Reason
Nov-30-2020 13:30:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-30-2020 13:30:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-30-2020 13:30:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: NO	Initial Entry

1.d

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/29/2020

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Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Nov-30-2020 13:30:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-30-2020 13:30:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-30-2020 13:30:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Nov-30-2020 13:30:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/29/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

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1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-30-2020 13:30:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: TELEPHONE CONSULTATIO N	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-30-2020 13:30:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Nov-30-2020 13:30:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Type of Practitioner: OTH ER Occurrence of Visits or Contacts: NO	Initial Entry

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-30-2020 13:30:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-30-2020 13:30:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-02-2020 16:34:42 (UTC-06:00) Central	ACV0PFEINFP6000	(b)(4, (b)(6)	Query 1: Closed	Response satisfies query

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
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Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Time (US & Canada)		(b)(4),(b)(6)		
Dec-02-2020 16:09:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	These have been added
Dec-01-2020 18:48:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Opened	Clinical Query: As this subject was hospitalized, please enter on the CRF form any available information (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...). Please make every effort to obtain these information.
Nov-30-2020 13:30:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Has the subject been in intensive care due to potential COVID-19 illness? NO	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - Audit Trail
on Nov/29/2020

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Dec-01-2020 16:28:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History on Nov/29/2020

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

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Generated By: (b) (4)

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1. Hospitalization Category:

Date	Location	User	Value	Reason
Dec-01-2020 16:28:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HOSPITALIZATION STATUS	Initial Entry

2. Hospitalization Term:

Date	Location	User	Value	Reason
Dec-01-2020 16:28:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HOSPITAL	Initial Entry

3. Admission Date:

Date	Location	User	Value	Reason
Dec-01-2020 16:28:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/27/2020	Initial Entry

4. Ongoing?

Date	Location	User	Value	Reason
Jan-06-2021 09:15:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Closed	Response satisfies query
Jan-05-2021 14:59:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Jan-05-2021 14:59:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Discharge Date: Dec/2/2020	New Information
Dec-23-2020 10:55:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Opened	Clin: Please enter end date for hospitalization.

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - eCRF Audit Trail History on Nov/29/2020

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Site No: 1107

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Generated By: (b) (4)

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Dec-01-2020 16:28:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: RESPIRATORY TREATMENT - eCRF Audit Trail History on Nov/29/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Nov-30-2020 13:31:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Not Applicable	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Nov-30-2020 13:31:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Not Applicable	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Nov-30-2020 13:31:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Nov-30-2020 13:31:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Nov-30-2020 13:31:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Nov-30-2020 13:31:15	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry:	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History
on Nov/29/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

(UTC-06:00) Central
Time (US & Canada)

(b) (4), (b) (6)

Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - eCRF Audit Trail History on Nov/29/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Nov-30-2020 13:31:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNES S	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Dec-03-2020 09:59:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Respiratory Illness Diagnosis:</i> COLITIS Date of Diagnosis: Nov/30/2020	New Information
Nov-30-2020 13:31:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-30-2020 13:31:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: 3	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Nov/29/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Nov-30-2020 13:32:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Not Applicable	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Nov-30-2020 13:32:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Not Applicable	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Nov-30-2020 13:32:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Not Applicable	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-30-2020 13:32:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Not Applicable	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Nov/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY -
Audit Trail

Form Version: 30-Jul-2020 21:27

Form Status:

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

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Date	Location	User	Value	Reason
Feb-19-2021 14:48:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Query Resolution
Dec-02-2020 11:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Dec-02-2020 11:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: CLINICAL CHEMISTRY	Initial Entry
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Feb-22-2021 04:05:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2: Closed	Data strikethrough.
Feb-19-2021 14:48:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Query Resolution
Feb-10-2021 05:33:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM: Thanks for the response, please update abnormal record. Thank you.
Feb-09-2021 09:39:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Per completion guidelines "at a minimum" most abnormal should be recorded.
Feb-09-2021 06:03:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 2: Opened	Per completion guidelines, If multiple values were recorded on a single day, most abnormal should be

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

				recorded, Please review all data entered on 28Nov2020 and remove as applicable. Else clarify.
Dec-09-2020 00:34:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-08-2020 08:36:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-08-2020 08:36:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: MOBILE INFIRMARY MEDICAL CLINIC LAB, 5 MOBILE INFIRMARY DRIVE, MOBILE, AL	Transcription Error
Dec-06-2020 13:30:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4,(b)(6)	Query 1: Opened	DM :A carriage return is identified, please do not press enter key, just type lab name all in single line with comma separated.
Dec-02-2020 11:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MOBILE INFIRMARY MEDICAL CLINIC LAB 5 MOBILE INFIRMARY DRIVE MOBILE, AL	Initial Entry
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

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Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

Date	Location	User	Value	Reason
Dec-02-2020 11:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/28/2020	Initial Entry
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Dec-02-2020 11:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-02-2020 11:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 329 Test:: Not Applicable Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

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Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

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

Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done:: Lab Normal Range :	Initial Entry
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range Not Applicable :	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 11:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 329	Initial Entry
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Nov-30-2020 13:32:20 (UTC-06:00) Central	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

Time (US & Canada)

(b) (4), (b) (6)

5.a Result:

Date	Location	User	Value	Reason
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Dec-02-2020 11:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT DONE	Initial Entry
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.b

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

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

Dec-02-2020 11:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 30 Test:: Not Applicable Result:: 18 Not Done:: Lab Normal Range: <i>Low</i> 0 <i>High</i> 40 <i>Unit</i> U/L	Initial Entry
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done:: Lab Normal Range:	Initial Entry
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

5.b Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 11:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30	Initial Entry
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Dec-02-2020 11:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 18	Initial Entry
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Not Applicable	Initial Entry
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5.b LNMT

Date	Location	User	Value	Reason
Dec-02-2020 11:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0 <i>High</i> 40 <i>Unit</i> U/L	Initial Entry
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-02-2020 11:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 28 Test:: Not Applicable Result:: 32 Not Done::	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

			Lab Normal Range: <i>Low</i> 0 <i>High</i> 40 <i>Unit</i> U/L	
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done:: Lab Normal Range:	Initial Entry
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

5.c Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 11:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 28	Initial Entry
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Dec-02-2020 11:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 32	Initial Entry
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Not Applicable	Initial Entry
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5.c LNMT

Date	Location	User	Value	Reason
Dec-02-2020 11:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0 <i>High</i> 40 <i>Unit</i> U/L	Initial Entry
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-02-2020 11:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 35 Test:: Not Applicable Result:: 94 Not Done::	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

			Lab Normal Range: <i>Low</i> 30 <i>High</i> 115 <i>Unit</i> U/L	
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done:: Lab Normal Range:	Initial Entry
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

5.d Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 11:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 35	Initial Entry
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

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Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

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5.d Test:

Date	Location	User	Value	Reason
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Dec-02-2020 11:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 94	Initial Entry
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Dec-02-2020 11:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Low 30	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Site No: 1107

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Subject Initials: ---

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			High 115	
			Unit U/L	
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Dec-02-2020 11:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 21 Test:: Not Applicable Result:: 0.3 Not Done:: Lab Normal Range: Low 0.2 High 1.2 Unit mg/dL	Initial Entry
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done:: Lab Normal Range: :	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Site Name: (1107) Coastal Clinical Research

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Subject Initials: ---

Generated By: (b) (4)

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

Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range : Not Applicable	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Form Status: Data Complete, Deleted, Frozen

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Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

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5.e Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 11:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 21	Initial Entry
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Dec-02-2020 11:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 0.3	Initial Entry
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Subject Initials: ---

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Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Not Applicable	Initial Entry
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5.e LNMT

Date	Location	User	Value	Reason
Dec-02-2020 11:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.2 <i>High</i> 1.2 <i>Unit</i> mg/dL	Initial Entry
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Dec-02-2020 11:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 47 Test:: Not Applicable Result:: 10 Not Done::	Initial Entry

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Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

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			Lab Normal Range: <i>Low</i> 5 <i>High</i> 25 <i>Unit</i> mg/dL	
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done:: Lab Normal Range:	Initial Entry
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Site Name: (1107) Coastal Clinical Research

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Subject Initials: ---

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

5.f Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 11:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 47	Initial Entry
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Dec-02-2020 11:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 10	Initial Entry
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

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

Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Not Applicable	Initial Entry
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5.f LNMT

Date	Location	User	Value	Reason
Dec-02-2020 11:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 5 <i>High</i> 25 <i>Unit</i> mg/dL	Initial Entry
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4, (b)(6)	Data Entry: Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
Dec-02-2020 11:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined I 48 dentifier: Test:: Not Applic able Result:: 0.73 Not Done::	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Site Name: (1107) Coastal Clinical Research

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Subject Initials: ---

Generated By: (b) (4)

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			Lab Normal Range: <i>Low</i> 0.51 <i>High</i> 0.95 <i>Unit</i> mg/dL	
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done:: Lab Normal Range:	Initial Entry
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

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Site Name: (1107) Coastal Clinical Research

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Generated By: (b) (4)

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5.g Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 11:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 48	Initial Entry
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Dec-02-2020 11:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 0.73	Initial Entry
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

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Date	Location	User	Value	Reason
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Dec-02-2020 11:01:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.51 <i>High</i> 0.95 <i>Unit</i> mg/dL	Initial Entry
Dec-02-2020 10:53:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

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Subject Initials: ---

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Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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Header Text: c4591001

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Site No: 1107

Site Name: (1107) Coastal Clinical Research

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Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Lab Panel:

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: CLINICAL CHEMISTRY	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Dec-09-2020 02:00:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Closed as data updated.
Dec-08-2020 08:40:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-08-2020 08:40:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: MOBILE INFIRMARY MEDICAL CLINIC LAB, 5 MOBILE INFIRMARY CIRCLE, MOBILE, AL	Transcription Error
Dec-06-2020 13:33:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM :A carriage return is identified, please do not press enter key, just type lab name all in single line with comma separated.
Dec-02-2020 11:06:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MOBILE INFIRMARY MEDICAL CLINIC LAB 5 MOBILE INFIRMARY CIRCLE MOBILE, AL	Transcription Error
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MOBILE INFIRMARY MEDICAL CLINIC 5 MOBILE INFIRMARY CIRCLE	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1107

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Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

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			MOBILE, AL	
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3. Collection Date:

Date	Location	User	Value	Reason
Feb-22-2021 02:55:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Closed	one record observed closed.
Feb-19-2021 14:48:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-10-2021 12:25:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Reissued:Opened	Only the most abnormal record is expected to be entered per date. please check and update data as appropriate. Please reach out to CRA if assistance is required.
Feb-09-2021 09:40:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Per completion guidelines "at a minimum" most abnormal should be recorded.
Feb-09-2021 06:03:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	Per completion guidelines, If multiple values were recorded on a single day, most abnormal should be recorded, Please review all data entered on 28Nov2020 and remove as applicable. Else clarify.
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/28/2020	Initial Entry

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020**Form Version:** 10-Oct-2020 15:58**Site No:** 1107**Subject No:** 11071031**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1107) Coastal Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:49**4. Specimen Type:**

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined 329 Identifier: Test:: C Reactive Prot ein_PX329 Result:: Not Done:: NOT DONE Lab Normal Ra nge:	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 329	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: C Reactive Protein_PX329	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NOT DONE	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

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Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

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Subject Initials: ---

Generated By: (b) (4)

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5.b

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Alanine Aminotransferase_PX30 Result:: 11 Not Done: Lab Normal Range: <i>Low</i> 0 <i>High</i> 40 <i>Unit</i> U/L	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:58**Form Status:** Data Complete, Frozen, Verified**Site No:** 1107**Site Name:** (1107) Coastal Clinical Research**Subject No:** 11071031**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Alanine Aminotransferase_PX30	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 11	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0 <i>High</i> 40 <i>Unit</i> U/L	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 28 Test:: Aspartate Aminotransferase_PX28	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Result:: 17	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			0	
			<i>High</i>	
			40	
			<i>Unit</i>	
			U/L	

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:58**Form Status:** Data Complete, Frozen, Verified**Site No:** 1107**Site Name:** (1107) Coastal Clinical Research**Subject No:** 11071031**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 28	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aspartate Aminotransferase_PX2 8	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 17	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0 <i>High</i> 40 <i>Unit</i> U/L	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Define 35 d Identifier: Test:: Alkaline Phosph atase_PX35	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Result:: 73	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			30	
			<i>High</i>	
			115	
			<i>Unit</i>	
			U/L	

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:58**Form Status:** Data Complete, Frozen, Verified**Site No:** 1107**Site Name:** (1107) Coastal Clinical Research**Subject No:** 11071031**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 35	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Alkaline Phosphatase_PX35	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 73	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 30 <i>High</i> 115 <i>Unit</i> U/L	Initial Entry

5.e

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Bilirubin_P X21	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Result:: 0.3	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			0.2	
			<i>High</i>	
			1.2	
			<i>Unit</i>	
			mg/dL	

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020**Form Version:** 10-Oct-2020 15:58**Site No:** 1107**Subject No:** 11071031**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1107) Coastal Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:49**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 21	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bilirubin_PX21	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.3	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.2 <i>High</i> 1.2 <i>Unit</i> mg/dL	Initial Entry

5.f

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Define 47 d Identifier: Test:: Blood Urea Nitr ogen_PX47	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Result:: 11	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			5	
			<i>High</i>	
			25	
			<i>Unit</i>	
			mg/dL	

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020**Form Version:** 10-Oct-2020 15:58**Site No:** 1107**Subject No:** 11071031**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1107) Coastal Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:49**5.f Sponsor ID:**

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 47	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Blood Urea Nitrogen_PX47	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 11	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 5 <i>High</i> 25 <i>Unit</i> mg/dL	Initial Entry

5.g

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id 48 entifier: Test:: Creatinine_P X48	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Nov/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY -
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Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Result:: 0.81	
			Not Done::	
			Lab Normal Range <i>Low</i>	
			:	0.51
				<i>High</i>
				0.95
			<i>Unit</i>	
			mg/dL	

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.g Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 48	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Creatinine_PX48	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.81	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Dec-02-2020 11:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.51 <i>High</i> 0.95 <i>Unit</i> mg/dL	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Lab Panel:

Date	Location	User	Value	Reason
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: CLINICAL CHEMISTRY	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Dec-09-2020 06:37:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-08-2020 08:43:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-08-2020 08:43:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MOBILE INFIRMARY MEDICAL CLINIC LAB, 5 MOBILE INFIRMARY CIRCLE, MOBILE, AL	Transcription Error
Dec-06-2020 13:33:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM :A carriage return is identified, please do not press enter key, just type lab name all in single line with comma separated.
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MOBILE INFIRMARY MEDICAL CLINIC LAB 5 MOBILE INFIRMARY CIRCLE MOBILE, AL	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
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090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

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Site No: 1107

Site Name: (1107) Coastal Clinical Research

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Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/29/2020	Initial Entry
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4. Specimen Type:

Date	Location	User	Value	Reason
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined 329 Identifier: Test:: C Reactive Protein_PX329 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 329	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C Reactive Protein_PX329	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

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Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry
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5.b

Date	Location	User	Value	Reason
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 30 Test:: Alanine Aminotransferase_PX30 Result:: 10 Not Done:: Lab Normal Range: <i>Low</i> 0 <i>High</i> 40 <i>Unit</i> U/L	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.b Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Alanine Aminotransferase_PX30	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 10	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0 <i>High</i> 40 <i>Unit</i> U/L	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 28 Test:: Aspartate Aminotransferase_PX28	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Result:: 15	
			Not Done::	
			Lab Normal R <i>Low</i>	
			ange: 0	
			<i>High</i>	
			40	
			<i>Unit</i>	
			U/L	

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:58**Form Status:** Data Complete, Frozen, Verified**Site No:** 1107**Site Name:** (1107) Coastal Clinical Research**Subject No:** 11071031**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 28	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aspartate Aminotransferase_PX2 8	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 15	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0 <i>High</i> 40 <i>Unit</i> U/L	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Define 35 d Identifier: Test:: Alkaline Phosph atase_PX35	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Result:: 64	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			30	
			<i>High</i>	
			115	
			<i>Unit</i>	
			U/L	

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:58**Form Status:** Data Complete, Frozen, Verified**Site No:** 1107**Site Name:** (1107) Coastal Clinical Research**Subject No:** 11071031**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 35	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Alkaline Phosphatase_PX35	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 64	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 30 <i>High</i> 115 <i>Unit</i> U/L	Initial Entry

5.e

Date	Location	User	Value	Reason
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Bilirubin_P X21	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Nov/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY -
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Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Result:: 0.2	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			0.2	
			<i>High</i>	
			1.2	
			<i>Unit</i>	
			mg/dL	

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020**Form Version:** 10-Oct-2020 15:58**Site No:** 1107**Subject No:** 11071031**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1107) Coastal Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:49**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 21	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bilirubin_PX21	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.2	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.2 <i>High</i> 1.2 <i>Unit</i> mg/dL	Initial Entry

5.f

Date	Location	User	Value	Reason
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Define 47 d Identifier: Test:: Blood Urea Nitr ogen_PX47	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Result:: 5	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			5	
			<i>High</i>	
			25	
			<i>Unit</i>	
			mg/dL	

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:58**Form Status:** Data Complete, Frozen, Verified**Site No:** 1107**Site Name:** (1107) Coastal Clinical Research**Subject No:** 11071031**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49**5.f Sponsor ID:**

Date	Location	User	Value	Reason
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 47	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Blood Urea Nitrogen_PX47	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 5	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 5 <i>High</i> 25 <i>Unit</i> mg/dL	Initial Entry

5.g

Date	Location	User	Value	Reason
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id 48 entifier: Test:: Creatinine_P X48	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
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Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY -
eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Result:: 0.71	
			Not Done::	
			Lab Normal Range <i>Low</i>	
			:	0.51
				<i>High</i>
				0.95
			<i>Unit</i>	
			mg/dL	

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

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Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.g Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 48	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Creatinine_PX48	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.71	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Dec-02-2020 11:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.51 <i>High</i> 0.95 <i>Unit</i> mg/dL	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Lab Panel:

Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: CLINICAL CHEMISTRY	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Dec-09-2020 06:36:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-08-2020 08:44:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-08-2020 08:44:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MOBILE INFIRMARY MEDICAL CLINIC LAB, 5 MOBILE INFIRMARY CIRCLE, MOBILE, AL	Transcription Error
Dec-06-2020 13:33:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM :A carriage return is identified, please do not press enter key, just type lab name all in single line with comma separated.
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MOBILE INFIRMARY MEDICAL CLINIC LAB 5 MOBILE INFIRMARY CIRCLE MOBILE, AL	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
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090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020**Form Version:** 10-Oct-2020 15:58**Site No:** 1107**Subject No:** 11071031**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1107) Coastal Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:49

Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/30/2020	Initial Entry
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4. Specimen Type:

Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined 329 Identifier: Test:: C Reactive Prot ein_PX329 Result:: Not Done:: NOT DONE Lab Normal Ra nge:	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 329	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C Reactive Protein_PX329	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

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Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

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Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry
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5.b

Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 30 Test:: Alanine Aminotransferase_PX30 Result:: 12 Not Done:: Lab Normal Range: <i>Low</i> 0 <i>High</i> 40 <i>Unit</i> U/L	Initial Entry

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020**Form Version:** 10-Oct-2020 15:58**Site No:** 1107**Subject No:** 11071031**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1107) Coastal Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:49**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Alanine Aminotransferase_PX30	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 12	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0 <i>High</i> 40 <i>Unit</i> U/L	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defin 28 ed Identifier: Test:: Aspartate Aminotransferase_PX28	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Form Status: Data Complete, Frozen, Verified

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Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Result:: 19	
			Not Done::	
			Lab Normal R <i>Low</i>	
			ange: 0	
			<i>High</i>	
			40	
			<i>Unit</i>	
			U/L	

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:58**Form Status:** Data Complete, Frozen, Verified**Site No:** 1107**Site Name:** (1107) Coastal Clinical Research**Subject No:** 11071031**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 28	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aspartate Aminotransferase_PX2 8	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 19	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0 <i>High</i> 40 <i>Unit</i> U/L	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Define 35 d Identifier: Test:: Alkaline Phosph atase_PX35	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

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			Result:: 69	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			30	
			<i>High</i>	
			115	
			<i>Unit</i>	
			U/L	

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.d Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 35	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Alkaline Phosphatase_PX35	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 69	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 30 <i>High</i> 115 <i>Unit</i> U/L	Initial Entry

5.e

Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Bilirubin_P X21	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Result:: 0.2	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			0.2	
			<i>High</i>	
			1.2	
			<i>Unit</i>	
			mg/dL	

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020**Form Version:** 10-Oct-2020 15:58**Site No:** 1107**Subject No:** 11071031**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1107) Coastal Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:49**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 21	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bilirubin_PX21	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.2	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.2 <i>High</i> 1.2 <i>Unit</i> mg/dL	Initial Entry

5.f

Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Define 47 d Identifier: Test:: Blood Urea Nitr ogen_PX47	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Result:: 2	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			5	
			<i>High</i>	
			25	
			<i>Unit</i>	
			mg/dL	

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:58**Form Status:** Data Complete, Frozen, Verified**Site No:** 1107**Site Name:** (1107) Coastal Clinical Research**Subject No:** 11071031**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49**5.f Sponsor ID:**

Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 47	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Blood Urea Nitrogen_PX47	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 5 <i>High</i> 25 <i>Unit</i> mg/dL	Initial Entry

5.g

Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id 48 entifier: Test:: Creatinine_P X48	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Nov/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY -
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Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Result:: 0.73	
			Not Done::	
			Lab Normal Range <i>Low</i>	
			:	0.51
				<i>High</i>
				0.95
			<i>Unit</i>	
			mg/dL	

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

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Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

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5.g Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 48	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Creatinine_PX48	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.73	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Dec-02-2020 11:12:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.51 <i>High</i> 0.95 <i>Unit</i> mg/dL	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Nov/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology -
Audit Trail

Form Version: 30-Jul-2020 21:28

Form Status:

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Date	Location	User	Value	Reason
Feb-19-2021 14:46:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Deleted	Query Response
Dec-02-2020 12:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Created	

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

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1. Lab Panel:

Date	Location	User	Value	Reason
Dec-02-2020 12:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HEMATOLOGY	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Dec-09-2020 03:03:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-08-2020 08:44:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-08-2020 08:44:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MOBILE INFIRMARY MEDICAL CLINIC LAB, 5 MOBILE INFIRMARY CIRCLE, MOBILE, AL 36607	Transcription Error
Dec-06-2020 13:30:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM :A carriage return is identified, please do not press enter key, just type lab name all in single line with comma separated.
Dec-02-2020 12:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MOBILE INFIRMARY MEDICAL CLINIC LAB	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

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Subject Initials: ---

Generated By: (b) (4)

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			5 MOBILE INFIRMARY CIRCLE MOBILE, AL 36607	
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-22-2021 01:05:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	data deleted
Feb-19-2021 14:46:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Query Response
Feb-10-2021 02:41:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	One the same day, most abnormal should be recorded, Please review all data entered on 28Nov2020 and remove as applicable.
Feb-09-2021 09:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Per completion guidelines "at a minimum" most abnormal should be recorded.
Feb-09-2021 06:04:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	Per completion guidelines, If multiple values were recorded on a single day, most abnormal should be recorded, Please

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:28**Form Status:** Data Complete, Deleted, Frozen**Site No:** 1107**Site Name:** (1107) Coastal Clinical Research**Subject No:** 11071031**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49***** THIS REPEATING FORM HAS BEEN DELETED *****

				review all data entered on 28Nov2020 and remove as applicable. Else clarify.
Dec-02-2020 12:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/28/2020	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Dec-02-2020 12:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry:	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-02-2020 12:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined I 1 identifier: Test:: Not Applicable Result:: 12.0	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

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Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

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

			Not Done:: Lab Normal Range <i>Low</i> : 12.0 <i>High</i> 14.0 <i>Unit</i> g/dL	
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done:: Lab Normal Range :	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range Not Applicable : cable	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 12:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

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

Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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5.a Test:

Date	Location	User	Value	Reason
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Dec-02-2020 12:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 12.0	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Dec-02-2020 12:59:15 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Low	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

Time (US & Canada)			12.0 <i>High</i> 14.0 <i>Unit</i> g/dL	
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-02-2020 12:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Not Applicable Result:: 38 Not Done:: Lab Normal Range: <i>Low</i> 36 <i>High</i> 48 <i>Unit</i> %	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done::	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

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

			Lab Normal Range :	
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Appli entifier: cable Test:: Not Appli cable Result:: Not Appli cable Not Done:: Not Appli cable Lab Normal Range Not Appli : cable	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

5.b Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 12:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 2	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Dec-02-2020 12:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 38	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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5.b LNMT

Date	Location	User	Value	Reason
Dec-02-2020 12:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 36 <i>High</i> 48 <i>Unit</i> %	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-02-2020 12:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 3 Test:: Not Applicable Result:: 4.69 Not Done::	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

			Lab Normal Range: <i>Low</i> 4.20 <i>High</i> 5.40 <i>Unit</i> 10 ⁶ /cu mm	
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done:: Lab Normal Range:	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

5.c Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 12:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 3	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Dec-02-2020 12:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 4.69	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

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Generated Time (GMT): 29-Mar-2021 10:49

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Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry
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5.c LNMT

Date	Location	User	Value	Reason
Dec-02-2020 12:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 4.20 <i>High</i> 5.40 <i>Unit</i> 10 ⁶ /cu mm	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-02-2020 12:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 5 Test:: Not Applicable Result:: 216 Not Done::	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

			Lab Normal Range <i>Low</i> : 140 <i>High</i> 450 <i>Unit</i> 10 ^{^3} /uL	
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done:: Lab Normal Range :	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range Not Applicable :	Initial Entry

5.d Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 12:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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5.d Sponsor ID:

Date	Location	User	Value	Reason
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Dec-02-2020 12:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 216	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

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

5.d LNMT

Date	Location	User	Value	Reason
Dec-02-2020 12:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 140 <i>High</i> 450 <i>Unit</i> 10 ³ /uL	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Dec-02-2020 12:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 7 Test:: Not Applicable Result:: 10.3 Not Done:: Lab Normal Range <i>Low</i> : 5.0 <i>High</i> 10.0 <i>Unit</i> 10 ³ /uL	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id	Initial Entry

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Header Text: c4591001

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Site Name: (1107) Coastal Clinical Research

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Subject Initials: ---

Generated By: (b) (4)

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			entifier: Test:: Not Appli cable Result:: Not Done:: Lab Normal Range :	
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sponsor-Defined Id entifier: Not Appli cable Test:: Not Appli cable Result:: Not Appli cable Not Done:: Not Appli cable Lab Normal Range Not Appli cable :	Initial Entry

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Site No: 1107

Site Name: (1107) Coastal Clinical Research

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

5.e Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 12:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 7	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Dec-02-2020 12:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 10.3	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Site Name: (1107) Coastal Clinical Research

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Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry
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5.e LNMT

Date	Location	User	Value	Reason
Dec-02-2020 12:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 5.0 <i>High</i> 10.0 <i>Unit</i> 10^3/uL	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Dec-03-2020 10:01:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 608 Test:: Not Applicable Result:: 7.44 Not Done:: Lab Normal Range: <i>Low</i> 1.80 <i>High</i> 7.00	Transcription Error

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Dec-02-2020 13:02:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined I dentifier: 608 Test:: Not Applic able Result:: 72 Not Done:: Lab Normal Rang e: Low 35 High 90 Unit %	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined I dentifier: Test:: Not Appli cable Result:: Not Done:: Lab Normal Rang e:	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sponsor-Defined I dentifier: Not Appli cable Test:: Not Appli cable Result:: Not Appli cable Not Done:: Not Appli cable Lab Normal Rang e: Not Appli cable	Initial Entry

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Header Text: c4591001

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Site Name: (1107) Coastal Clinical Research

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Generated By: (b) (4)

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5.f Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 13:02:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 608	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Dec-04-2020 02:49:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-03-2020 14:41:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_LB001_08
Dec-03-2020 10:05:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	NO UNIT GIVEN IN MEDICAL RECORDS

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Subject No: 11071031

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Generated By: (b) (4)

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

Canada)				
Dec-03-2020 10:01:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Ope ned	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-03-2020 10:01:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Transcription Error
Dec-03-2020 10:01:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 7.44	Transcription Error
Dec-03-2020 02:21:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Ope ned	DMW6299285;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Dec-02-2020 13:02:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 72	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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5.f Not Done:

Date	Location	User	Value	Reason
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Dec-03-2020 10:01:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 1.80 <i>High</i> 7.00	Transcription Error
Dec-02-2020 13:02:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 35 <i>High</i> 90 <i>Unit</i> %	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:32:40	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry:	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

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

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	Not Applicable	
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5.g

Date	Location	User	Value	Reason
Dec-08-2020 08:46:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sponsor-Defined Identifier: 609 Test:: Not Applicable Result:: 0.07 Not Done:: Lab Normal Range <i>Low</i> : 0.00 <i>High</i> 0.70 <i>Unit</i> 10 ⁹ /L	Transcription Error

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

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5.g

Date	Location	User	Value	Reason
Dec-03-2020 10:02:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 609 Test:: Not Applicable Result:: 0.07 Not Done:: Lab Normal Range: <i>Low</i> 0.00 <i>High</i> 0.70	Transcription Error
Dec-02-2020 13:02:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 609 Test:: Not Applicable Result:: 1 Not Done:: Lab Normal Range: <i>Low</i> 0 <i>High</i> 8 <i>Unit</i> %	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Not Applicable Result::	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

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Site No: 1107

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

			Not Done:: Lab Normal Range:	
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

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5.g Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 13:02:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 609	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Dec-09-2020 01:03:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-08-2020 08:46:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Answer Auto Query
Dec-04-2020 03:30:57 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	DM: Please update as per available CRF options. Per section 8.39.4 of completion

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

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Site No: 1107

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(US & Canada)			d	guidelines, Neutrophils, Eosinophils, Monocytes, Basophils and Lymphocytes should be entered as absolute values using 10 ⁹ /L as units. Please update as appropriate.
Dec-03-2020 14:41:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_LB001_08
Dec-03-2020 10:06:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	NO UNIT IS GIVEN IN MEDICAL RECORDS
Dec-03-2020 10:02:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-03-2020 10:02:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-03-2020 10:02:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : 0.07	Transcription Error

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

Dec-03-2020 02:21:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query I: Op ened	DMW6299294;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Dec-02-2020 13:02:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> : 1	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> :	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> : Not A pplica ble	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
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090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

Dec-08-2020 08:46:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: <i>Low</i> 0.00 <i>High</i> 0.70 <i>Unit</i> 10^9/L	Transcription Error
Dec-03-2020 10:02:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.00 <i>High</i> 0.70	Transcription Error
Dec-02-2020 13:02:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0 <i>High</i> 8 <i>Unit</i> %	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

5.h

Date	Location	User	Value	Reason
Dec-08-2020 08:47:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sponsor-Defined Identifier: 612 Test:: Not Applicable	Transcription Error

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

			Result:: 1.01 Not Done:: Lab Normal Range: <i>Low</i> e: 0.00 <i>High</i> 0.80 <i>Unit</i> 10^9/L	
Dec-03-2020 10:02:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 612 Test:: Not Applicable Result:: 1.01 Not Done:: Lab Normal Range: <i>Low</i> e: 0.00 <i>High</i> 0.80	Transcription Error
Dec-02-2020 13:02:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 612 Test:: Not Applicable Result:: 10 Not Done:: Lab Normal Range: <i>Low</i> e: 0 <i>High</i> 14 <i>Unit</i> %	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

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Site No: 1107

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done:: Lab Normal Range:	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

5.h Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 13:02:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 612	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Dec-09-2020 02:03:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-08-2020 08:47:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Answer Auto Query
Dec-04-2020 03:31:46 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	DM: Please update as per available CRF options. Per section 8.39.4 of completion

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

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Site No: 1107

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(US & Canada)			d	guidelines, Neutrophils, Eosinophils, Monocytes, Basophils and Lymphocytes should be entered as absolute values using 10 ⁹ /L as units. Please update as appropriate.
Dec-03-2020 14:41:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_LB001_08
Dec-03-2020 10:06:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	NO UNIT IS GIVEN IN MEDICAL RECORDS
Dec-03-2020 10:02:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-03-2020 10:02:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-03-2020 10:02:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : 1.01	Transcription Error

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

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Generated By: (b) (4)

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

Dec-03-2020 02:21:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query I: Op ened	DMW6299293;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Dec-02-2020 13:02:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> : 10	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> :	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> : Not A pplica ble	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

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Generated Time (GMT): 29-Mar-2021 10:49

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5.h LNMT

Date	Location	User	Value	Reason
Dec-08-2020 08:47:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: <i>Low</i> 0.00 <i>High</i> 0.80 <i>Unit</i> 10^9/L	Transcription Error
Dec-03-2020 10:02:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.00 <i>High</i> 0.80	Transcription Error
Dec-02-2020 13:02:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0 <i>High</i> 14 <i>Unit</i> %	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

5.i

Date	Location	User	Value	Reason
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090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

Dec-08-2020 08:48:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sponsor-Defined Identifier: 610 Test:: Not Applicable Result:: 0.05 Not Done:: Lab Normal Range: <i>Low</i> 0.00 <i>High</i> 0.20 <i>Unit</i> 10^9/L	Transcription Error
Dec-03-2020 10:04:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 610 Test:: Not Applicable Result:: 0.05 Not Done:: Lab Normal Range: <i>Low</i> 0.00 <i>High</i> 0.20	Transcription Error
Dec-02-2020 13:02:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 610 Test:: Not Applicable Result:: 1 Not Done::	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

			Lab Normal Range: <i>Low</i> 0 <i>High</i> 2 <i>Unit</i> %	
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done:: Lab Normal Range:	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

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

5.i Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 13:02:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 610	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Dec-09-2020 02:04:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-08-2020 08:48:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Answer Auto Query
Dec-04-2020 03:32:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	DM: Please update as per available CRF options. Per section 8.39.4 of completion guidelines,

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

Canada)				Neutrophils, Eosinophils, Monocytes, Basophils and Lymphocytes should be entered as absolute values using 10 ⁹ /L as units. Please update as appropriate.
Dec-03-2020 14:41:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_LB001_08
Dec-03-2020 10:06:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	NO UNIT IS GIVEN IN MEDICAL RECORDS
Dec-03-2020 10:04:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-03-2020 10:04:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-03-2020 10:04:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.05	Transcription Error

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

Dec-03-2020 02:21:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6299282;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Dec-02-2020 13:02:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
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090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

Dec-08-2020 08:48:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: <i>Low</i> 0.00 <i>High</i> 0.20 <i>Unit</i> 10^9/L	Transcription Error
Dec-03-2020 10:04:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.00 <i>High</i> 0.20	Transcription Error
Dec-02-2020 13:02:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0 <i>High</i> 2 <i>Unit</i> %	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

5.j

Date	Location	User	Value	Reason
Dec-08-2020 08:51:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sponsor-Defined I 611 dentifier: Test:: Not Appli cable	Transcription Error

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

			Result:: 1.71 Not Done:: Lab Normal Range: <i>Low</i> e: 1.00 <i>High</i> 4.80 <i>Unit</i> 10^9/L	
Dec-03-2020 10:05:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 611 Test:: Not Applicable Result:: 1.71 Not Done:: Lab Normal Range: <i>Low</i> e: 1.00 <i>High</i> 4.80	Transcription Error
Dec-02-2020 13:02:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 611 Test:: Not Applicable Result:: 17 Not Done:: Lab Normal Range: <i>Low</i> e: 20 <i>High</i> 40 <i>Unit</i> %	Initial Entry
Dec-02-2020 11:15:02	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	Sponsor-Defined Identifier: Test:: Not Applicable Result:: Not Done:: Lab Normal Range:	
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

5.j Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 13:02:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 611	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Dec-09-2020 02:04:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: C losed	Response satisfies query
Dec-08-2020 08:51:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: A nswered	Answer Auto Query
Dec-04-2020 05:09:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: R eissued:Op ened	DM: Per section 8.39.4 of CRF completion guidelines, Neutrophils, Eosinophils, Monocytes,

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

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Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

				Basophils and Lymphocytes should be entered as absolute values using 10 ⁹ /L as units. Please review and update data as per available CRF options. Else clarify.
Dec-03-2020 14:41:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: C losed	Auto closed by Validation Check: VC_LB001_08
Dec-03-2020 10:06:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: A nswered	NO UNIT IS GIVEN IN MEDICAL RECORDS
Dec-03-2020 10:05:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: O pened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-03-2020 10:05:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: A nswered	Transcription Error
Dec-03-2020 10:05:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entr y: 1.71	Transcription Error

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

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5.j Result:

Date	Location	User	Value	Reason
Dec-03-2020 02:21:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6299295;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Dec-02-2020 13:02:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> : 17	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> :	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> : Not Applicable	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Not Applicable	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Deleted, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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

Time (US & Canada)	(b) (4), (b) (6)
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5.j LNMT

Date	Location	User	Value	Reason
Dec-08-2020 08:51:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: <i>Low</i> 1.00 <i>High</i> 4.80 <i>Unit</i> 10 ⁹ /L	Transcription Error
Dec-03-2020 10:05:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 1.00 <i>High</i> 4.80	Transcription Error
Dec-02-2020 13:02:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 20 <i>High</i> 40 <i>Unit</i> %	Initial Entry
Dec-02-2020 11:15:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:32:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Nov/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology -
Audit Trail

Form Version: 10-Oct-2020 16:02

Form Status:

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Nov/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology -
Audit Trail

Form Version: 10-Oct-2020 16:02

Form Status:

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Audit Trail

Form Version: 10-Oct-2020 16:02

Form Status:

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Lab Panel:

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HEMATOLOGY	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Dec-09-2020 06:36:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-08-2020 08:45:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-08-2020 08:45:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: MOBILE INFIRMARY MEDICAL CLINIC LAB, 5 MOBILE INFIRMARY CIRCLE, MOBILE, AL	Transcription Error
Dec-06-2020 13:34:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Query 1: Opened	DM :A carriage return is identified, please do not press enter key, just type lab name all in single line with comma separated.
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MOBILE INFIRMARY MEDICAL CLINIC LAB 5 MOBILE INFIRMARY CIRCLE MOBILE, AL	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-22-2021 06:40:17 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

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090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Time (US & Canada)		(b) (4), (b) (6)		
Feb-19-2021 14:46:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-10-2021 12:24:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Reissued:Opened	Only the most abnormal record is expected to be entered per date. please check and update data as appropriate. Please reach out to CRA if assistance is required.
Feb-09-2021 09:40:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Per completion guidelines "at a minimum" most abnormal should be recorded.
Feb-09-2021 06:04:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	Per completion guidelines, If multiple values were recorded on a single day, most abnormal should be recorded, Please review all data entered on 28Nov2020 and remove as applicable. Else clarify.
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/28/2020	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.a

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Hemoglobin _PX1 Result:: 9.8 Not Done: Lab Normal Range <i>Low</i> : 12.0 <i>High</i> 14.0 <i>Unit</i> g/dL	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hemoglobin_PX1	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 9.8	Initial Entry

5.a LNMT

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 12.0 <i>High</i> 14.0 <i>Unit</i> g/dL	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Hematocrit_PX2 Result:: 31 Not Done:: Lab Normal Range: <i>Low</i> 36 <i>High</i> 48 <i>Unit</i> %	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1107**Site Name:** (1107) Coastal Clinical Research**Subject No:** 11071031**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hematocrit_PX2	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 31	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 36 <i>High</i> 48 <i>Unit</i> %	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id 3 entifier: Test:: Erythrocytes _PX3	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Result:: 3.87	
			Not Done::	
			Lab Normal Range <i>Low</i>	
			:	4.20
			<i>High</i>	
			5.40	
			<i>Unit</i>	
			10 ⁶ /cu m	
			m	

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1107**Site Name:** (1107) Coastal Clinical Research**Subject No:** 11071031**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Erythrocytes_PX3	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3.87	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 4.20 <i>High</i> 5.40 <i>Unit</i> 10 ⁶ /cu mm	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 5 Test:: Platelets_P X5	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Result:: 309	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			140	
			<i>High</i>	
			450	
			<i>Unit</i>	
			10 ³ /uL	

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1107**Site Name:** (1107) Coastal Clinical Research**Subject No:** 11071031**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Platelets_PX5	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 309	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 140 <i>High</i> 450 <i>Unit</i> 10 ³ /uL	Initial Entry

5.e

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id 7 entifier: Test:: Leukocytes_ PX7	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Result:: 9.1	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			5.0	
			<i>High</i>	
			10.0	
			<i>Unit</i>	
			10 ³ /uL	

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1107**Site Name:** (1107) Coastal Clinical Research**Subject No:** 11071031**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Leukocytes_PX7	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 9.1	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 5.0 <i>High</i> 10.0 <i>Unit</i> 10 ³ /uL	Initial Entry

5.f

Date	Location	User	Value	Reason
Dec-08-2020 08:52:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sponsor-Defined Identifier: 608 Test:: Neutrophils_ PX608	Transcription Error

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Result:: 5.52 Not Done:: Lab Normal Range: <i>Low</i> 1.80 <i>High</i> 7.00 <i>Unit</i> 10 ⁹ /L	
Dec-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 608 Test:: Neutrophils_PX608 Result:: 5.52 Not Done:: Lab Normal Range: <i>Low</i> 1.80 <i>High</i> 7.00	Transcription Error
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 608 Test:: Neutrophils_PX608 Result:: 60 Not Done:: Lab Normal Range: <i>Low</i> 35 <i>High</i> 90 <i>Unit</i> %	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

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Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.f Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 608	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Neutrophils_PX608	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Dec-09-2020 06:41:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Closed	Response satisfies query
Dec-08-2020 08:52:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Answer Auto Query
Dec-03-2020 23:59:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	DM: Result is present. However, unit is missing. Please review and update the data. Kindly connect with CRA for any further assistance if needed.
Dec-03-2020 14:41:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_LB001_08

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

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Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Canada)				
Dec-03-2020 10:10:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Ans wered	NO UNIT IS GIVEN IN MEDICAL RECORDS
Dec-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Ope ned	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Transcription Error
Dec-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 5.52	Transcription Error
Dec-03-2020 02:21:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Ope ned	DMW6299280;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 60	Initial Entry

5.f LNMT

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

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Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Date	Location	User	Value	Reason
Dec-08-2020 08:52:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: <i>Low</i> 1.80 <i>High</i> 7.00 <i>Unit</i> 10^9/L	Transcription Error
Dec-03-2020 10:08:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 1.80 <i>High</i> 7.00	Transcription Error
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 35 <i>High</i> 90 <i>Unit</i> %	Initial Entry

5.g

Date	Location	User	Value	Reason
Dec-08-2020 09:11:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sponsor-Defined Identifier: 609 Test:: Eosinophils_ PX609 Result:: 0.07 Not Done::	Transcription Error

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

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Subject Initials: ---

Generated By: (b) (4)

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			Lab Normal Range: <i>Low</i> 0.00 <i>High</i> 0.70 <i>Unit</i> 10 ⁹ /L	
Dec-03-2020 10:08:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 609 Test:: Eosinophils_PX609 Result:: 0.07 Not Done:: Lab Normal Range: <i>Low</i> 0.00 <i>High</i> 0.70	Transcription Error
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 609 Test:: Eosinophils_PX609 Result:: 1 Not Done:: Lab Normal Range: <i>Low</i> 0 <i>High</i> 8 <i>Unit</i> %	Initial Entry

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Header Text: c4591001

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Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

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5.g Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 609	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Eosinophils_PX609	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Dec-09-2020 06:42:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Closed	Response satisfies query
Dec-08-2020 09:11:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Answer Auto Query

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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5.g Result:

Date	Location	User	Value	Reason
Dec-04-2020 00:00:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	DM: Result is present. However, unit is missing. Please review and update the data. Kindly connect with CRA for any further assistance if needed.
Dec-03-2020 14:41:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_LB001_08
Dec-03-2020 10:10:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	NO UNIT IS GIVEN IN MEDICAL RECORDS
Dec-03-2020 10:08:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-03-2020 10:08:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-03-2020 10:08:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : 0.07	Transcription Error

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Canada)				
Dec-03-2020 02:21:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6299281;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> : 1	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Dec-08-2020 09:11:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Low 0.00 High 0.70 Unit 10^9/L	Transcription Error
Dec-03-2020 10:08:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Low 0.00 High 0.70	Transcription Error
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Low 0 High 8	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Unit %	
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5.h

Date	Location	User	Value	Reason
Dec-08-2020 09:19:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sponsor-Defined Identifier: Test:: Monocytes_ PX612 Result:: 1.27 Not Done:: Lab Normal Range: <i>Low</i> 0.00 <i>High</i> 0.80 <i>Unit</i> 10^9/L	Transcription Error
Dec-03-2020 10:08:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Monocytes_ PX612 Result:: 1.27 Not Done:: Lab Normal Range: <i>Low</i> 0.00 <i>High</i> 0.80	Transcription Error
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Monocytes_ PX612 Result:: 14	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Not Done::	
			Lab Normal Range:	
			<i>Low</i>	
			0	
			<i>High</i>	
			14	
			<i>Unit</i>	
			%	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.h Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 612	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Monocytes_PX612	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Dec-09-2020 06:41:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Closed	Response satisfies query
Dec-08-2020 09:19:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Answer Auto Query
Dec-04-2020 00:00:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	DM: Result is present. However, unit is missing. Please review and update the data. Kindly connect with CRA for any further assistance if needed.
Dec-03-2020 14:41:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_LB001_08

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Canada)				
Dec-03-2020 10:10:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Ans wered	NO UNIT IS GIVEN IN MEDICAL RECORDS
Dec-03-2020 10:08:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Ope ned	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-03-2020 10:08:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Transcription Error
Dec-03-2020 10:08:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1.27	Transcription Error
Dec-03-2020 02:21:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Ope ned	DMW6299296;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 14	Initial Entry

5.h LNMT

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Date	Location	User	Value	Reason
Dec-08-2020 09:19:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: <i>Low</i> 0.00 <i>High</i> 0.80 <i>Unit</i> 10^9/L	Transcription Error
Dec-03-2020 10:08:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.00 <i>High</i> 0.80	Transcription Error
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0 <i>High</i> 14 <i>Unit</i> %	Initial Entry

5.i

Date	Location	User	Value	Reason
Dec-08-2020 09:19:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sponsor-Defined 610 Identifier: Test:: Basophils_P X610 Result:: 0.04 Not Done::	Transcription Error

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Lab Normal Range: <i>Low</i> 0.00 <i>High</i> 0.20 <i>Unit</i> 10 ⁹ /L	
Dec-03-2020 10:09:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 610 Test:: Basophils_P X610 Result:: 0.04 Not Done:: Lab Normal Range: <i>Low</i> 0.00 <i>High</i> 0.20	Transcription Error
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 610 Test:: Basophils_P X610 Result:: 0 Not Done:: Lab Normal Range: <i>Low</i> 0 <i>High</i> 2 <i>Unit</i> %	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.i Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 610	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Basophils_PX610	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Dec-09-2020 00:25:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-08-2020 09:19:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Answer Auto Query
Dec-04-2020 00:01:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	DM: Result is present. However, unit is missing. Please review and update the data. Kindly connect with CRA for any further assistance if needed.
Dec-03-2020 14:41:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_LB001_08

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Canada)				
Dec-03-2020 10:10:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Ans wered	NO UNIT IS GIVEN IN MEDICAL RECORDS
Dec-03-2020 10:09:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Ope ned	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-03-2020 10:09:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Transcription Error
Dec-03-2020 10:09:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.04	Transcription Error
Dec-03-2020 02:21:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Ope ned	DMW6299286;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0	Initial Entry

5.i LNMT

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Date	Location	User	Value	Reason
Dec-08-2020 09:19:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: <i>Low</i> 0.00 <i>High</i> 0.20 <i>Unit</i> 10 ⁹ /L	Transcription Error
Dec-03-2020 10:09:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.00 <i>High</i> 0.20	Transcription Error
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0 <i>High</i> 2 <i>Unit</i> %	Initial Entry

5.j

Date	Location	User	Value	Reason
Dec-08-2020 09:20:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sponsor-Defined 611 Identifier: Test:: Lymphocytes _PX611 Result:: 2.14 Not Done::	Transcription Error

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Lab Normal Range: <i>Low</i> 1.00 <i>High</i> 4.80 <i>Unit</i> 10 ⁹ /L	
Dec-03-2020 10:09:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 611 Test:: Lymphocytes_PX611 Result:: 2.14 Not Done:: Lab Normal Range: <i>Low</i> 1.00 <i>High</i> 4.80	Transcription Error
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 611 Test:: Lymphocytes_PX611 Result:: 24 Not Done:: Lab Normal Range: <i>Low</i> 20 <i>High</i> 40 <i>Unit</i> %	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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5.j Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 611	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Lymphocytes_PX611	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Dec-09-2020 00:25:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Clos ed	Response satisfies query
Dec-08-2020 09:20:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Ans wered	Answer Auto Query
Dec-04-2020 00:01:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reis sued:O pened	DM: Result is present. However, unit is missing. Please review and update the data. Kindly connect with CRA for any further assistance if needed.
Dec-03-2020 14:41:33 (UTC-06:00)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Clos ed	Auto closed by Validation Check: VC_LB001_08

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Central Time (US & Canada)				
Dec-03-2020 10:10:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	NO UNIT IS GIVEN IN MEDICAL RECORDS
Dec-03-2020 10:09:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-03-2020 10:09:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-03-2020 10:09:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2.14	Transcription Error
Dec-03-2020 02:21:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6299289;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.j LNMT

Date	Location	User	Value	Reason
Dec-08-2020 09:20:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: <i>Low</i> 1.00 <i>High</i> 4.80 <i>Unit</i> 10^9/L	Transcription Error
Dec-03-2020 10:09:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 1.00 <i>High</i> 4.80	Transcription Error
Dec-02-2020 13:08:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 20 <i>High</i> 40 <i>Unit</i> %	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Lab Panel:

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HEMATOLOGY	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Dec-09-2020 01:48:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Closed as data updated.
Dec-08-2020 08:43:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-08-2020 08:43:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: MOBILE INFIRMARY MEDICAL CLINIC LAB,5 MOBILE INFIRMARY CIRCLE, MOBILE, AL	Transcription Error
Dec-06-2020 13:34:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Opened	DM :A carriage return is identified, please do not press enter key, just type lab name all in single line with comma separated.
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MOBILE INFIRMARY MEDICAL CLINIC LAB 5 MOBILE INFIRMARY CIRCLE MOBILE, AL	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
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090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/29/2020	Initial Entry
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4. Specimen Type:

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id 1 entifier: Test:: Hemoglobin _PX1 Result:: 9.6 Not Done:: Lab Normal Range <i>Low</i> : 12.0 <i>High</i> 14.0 <i>Unit</i> g/dL	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hemoglobin_PX1	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Time (US & Canada)				
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5.a Result:

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 9.6	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 12.0 <i>High</i> 14.0 <i>Unit</i> g/dL	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Hematocrit_PX2 Result:: 30 Not Done:: Lab Normal Range: <i>Low</i> 36 <i>High</i> 48 <i>Unit</i> %	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1107**Site Name:** (1107) Coastal Clinical Research**Subject No:** 11071031**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hematocrit_PX2	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 30	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 36 <i>High</i> 48 <i>Unit</i> %	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id 3 entifier: Test:: Erythrocytes _PX3	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Result:: 3.76	
			Not Done::	
			Lab Normal Range <i>Low</i>	
			:	4.20
			<i>High</i>	
			5.40	
			<i>Unit</i>	
			10 ⁶ /cu m	
			m	

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1107**Site Name:** (1107) Coastal Clinical Research**Subject No:** 11071031**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Erythrocytes_PX3	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3.76	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 4.20 <i>High</i> 5.40 <i>Unit</i> 10 ⁶ /cu mm	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 5 Test:: Platelets_P X5	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Result:: 321	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			140	
			<i>High</i>	
			450	
			<i>Unit</i>	
			10 ³ /uL	

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1107**Site Name:** (1107) Coastal Clinical Research**Subject No:** 11071031**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Platelets_PX5	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 321	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 140 <i>High</i> 450 <i>Unit</i> 10 ³ /uL	Initial Entry

5.e

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id 7 entifier: Test:: Leukocytes_ PX7	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Result:: 7.4	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			5.0	
			<i>High</i>	
			10.0	
			<i>Unit</i>	
			10 ³ /uL	

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1107**Site Name:** (1107) Coastal Clinical Research**Subject No:** 11071031**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Leukocytes_PX7	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 7.4	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 5.0 <i>High</i> 10.0 <i>Unit</i> 10 ³ /uL	Initial Entry

5.f

Date	Location	User	Value	Reason
Dec-08-2020 10:10:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sponsor-Defined Identifier: 608 Test:: Neutrophils_ PX608	Transcription Error

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Result:: 4.18 Not Done:: Lab Normal Range: <i>Low</i> 1.80 <i>High</i> 7.00 <i>Unit</i> 10 ⁹ /L	
Dec-03-2020 10:12:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 608 Test:: Neutrophils_PX608 Result:: 4.18 Not Done:: Lab Normal Range: <i>Low</i> 1.80 <i>High</i> 7.00	Transcription Error
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 608 Test:: Neutrophils_PX608 Result:: 57 Not Done:: Lab Normal Range: <i>Low</i> 35 <i>High</i> 90 <i>Unit</i> %	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

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Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.f Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 608	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Neutrophils_PX608	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Dec-09-2020 01:50:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Closed as data updated.
Dec-08-2020 10:10:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Answer Auto Query
Dec-04-2020 02:11:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2: Reissued: Opened	DM: Result is present. However, unit is missing. Please review and update the data. Kindly connect with CRA for any further assistance if needed.
Dec-03-2020 14:41:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_LB001_08

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

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Site No: 1107

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Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Canada)				
Dec-03-2020 10:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Ans wered	NO UNIT IS GIVEN IN MEDICAL RECORDS
Dec-03-2020 10:12:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Ope ned	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-03-2020 10:12:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Transcription Error
Dec-03-2020 10:12:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4.18	Transcription Error
Dec-03-2020 02:21:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Ope ned	DMW6299290;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 57	Initial Entry

5.f LNMT

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Date	Location	User	Value	Reason
Dec-08-2020 10:10:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: <i>Low</i> 1.80 <i>High</i> 7.00 <i>Unit</i> 10^9/L	Transcription Error
Dec-03-2020 10:12:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 1.80 <i>High</i> 7.00	Transcription Error
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 35 <i>High</i> 90 <i>Unit</i> %	Initial Entry

5.g

Date	Location	User	Value	Reason
Dec-08-2020 10:11:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sponsor-Defined Identifier: 609 Test:: Eosinophils_ PX609 Result:: 0.13 Not Done::	Transcription Error

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Lab Normal Range: <i>Low</i> 0.00 <i>High</i> 0.70 <i>Unit</i> 10 ⁹ /L	
Dec-03-2020 10:12:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 609 Test:: Eosinophils_PX609 Result:: 0.13 Not Done:: Lab Normal Range: <i>Low</i> 0.00 <i>High</i> 0.70	Transcription Error
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 609 Test:: Eosinophils_PX609 Result:: 2 Not Done:: Lab Normal Range: <i>Low</i> 0 <i>High</i> 8 <i>Unit</i> %	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.g Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 609	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Eosinophils_PX609	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Dec-09-2020 04:37:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 2: Closed	Response satisfies query
Dec-08-2020 10:11:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Answer Auto Query

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

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5.g Result:

Date	Location	User	Value	Reason
Dec-04-2020 02:11:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2: Reissued: Opened	DM: Result is present. However, unit is missing. Please review and update the data. Kindly connect with CRA for any further assistance if needed.
Dec-03-2020 14:41:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_LB001_08
Dec-03-2020 10:14:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	NO UNIT IS GIVEN IN MEDICAL RECORDS
Dec-03-2020 10:12:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-03-2020 10:12:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-03-2020 10:12:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : 0.13	Transcription Error

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Canada)				
Dec-03-2020 02:21:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6299291;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : 2	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Dec-08-2020 10:11:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: <i>Low</i> 0.00 <i>High</i> 0.70 <i>Unit</i> 10^9/L	Transcription Error
Dec-03-2020 10:12:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.00 <i>High</i> 0.70	Transcription Error
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0 <i>High</i> 8	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

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			Unit %	
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5.h

Date	Location	User	Value	Reason
Dec-08-2020 10:11:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sponsor-Defined Identifier: Test:: Monocytes_ PX612 Result:: 1.22 Not Done:: Lab Normal Range: <i>Low</i> 0.00 <i>High</i> 0.80 <i>Unit</i> 10^9/L	Transcription Error
Dec-03-2020 10:13:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Monocytes_ PX612 Result:: 1.22 Not Done:: Lab Normal Range: <i>Low</i> 0.00 <i>High</i> 0.80	Transcription Error
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Monocytes_ PX612 Result:: 16	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

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Form Status: Data Complete, Frozen, Verified

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Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Not Done::	
			Lab Normal Range:	
			<i>Low</i>	
			0	
			<i>High</i>	
			14	
			<i>Unit</i>	
			%	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

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Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.h Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 612	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Monocytes_PX612	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Dec-09-2020 04:37:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-08-2020 10:11:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Answer Auto Query
Dec-04-2020 02:11:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2: Reissued: Opened	DM: Result is present. However, unit is missing. Please review and update the data. Kindly connect with CRA for any further assistance if needed.
Dec-03-2020 14:41:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_LB001_08

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Canada)				
Dec-03-2020 10:14:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Ans wered	NO UNIT IS GIVEN IN MEDICAL RECORDS
Dec-03-2020 10:13:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Ope ned	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-03-2020 10:13:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Transcription Error
Dec-03-2020 10:13:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1.22	Transcription Error
Dec-03-2020 02:21:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Ope ned	DMW6299297;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 16	Initial Entry

5.h LNMT

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Date	Location	User	Value	Reason
Dec-08-2020 10:11:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: <i>Low</i> 0.00 <i>High</i> 0.80 <i>Unit</i> 10^9/L	Transcription Error
Dec-03-2020 10:13:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.00 <i>High</i> 0.80	Transcription Error
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0 <i>High</i> 14 <i>Unit</i> %	Initial Entry

5.i

Date	Location	User	Value	Reason
Dec-08-2020 10:12:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sponsor-Defined Identifier: 610 Test:: Basophils_P X610 Result:: 0.03 Not Done::	Transcription Error

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Lab Normal Range: <i>Low</i> 0.00 <i>High</i> 0.20 <i>Unit</i> 10 ⁹ /L	
Dec-03-2020 10:13:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 610 Test:: Basophils_P X610 Result:: 0.03 Not Done:: Lab Normal Range: <i>Low</i> 0.00 <i>High</i> 0.20	Transcription Error
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 610 Test:: Basophils_P X610 Result:: 0 Not Done:: Lab Normal Range: <i>Low</i> 0 <i>High</i> 2 <i>Unit</i> %	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.i Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 610	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Basophils_PX610	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Dec-09-2020 04:37:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-08-2020 10:12:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Answer Auto Query
Dec-04-2020 02:11:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2: Reissued: Opened	DM: Result is present. However, unit is missing. Please review and update the data. Kindly connect with CRA for any further assistance if needed.
Dec-03-2020 14:41:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_LB001_08

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Canada)				
Dec-03-2020 10:14:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Ans wered	NO UNIT IS GIVEN IN MEDICAL RECORDS
Dec-03-2020 10:13:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Ope ned	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-03-2020 10:13:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Transcription Error
Dec-03-2020 10:13:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.03	Transcription Error
Dec-03-2020 02:21:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Ope ned	DMW6299292;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0	Initial Entry

5.i LNMT

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Date	Location	User	Value	Reason
Dec-08-2020 10:12:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: <i>Low</i> 0.00 <i>High</i> 0.20 <i>Unit</i> 10^9/L	Transcription Error
Dec-03-2020 10:13:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.00 <i>High</i> 0.20	Transcription Error
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0 <i>High</i> 2 <i>Unit</i> %	Initial Entry

5.j

Date	Location	User	Value	Reason
Dec-08-2020 10:12:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sponsor-Defined 611 Identifier: Test:: Lymphocytes _PX611 Result:: 1.84 Not Done::	Transcription Error

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Lab Normal Range: <i>Low</i> 1.00 <i>High</i> 4.80 <i>Unit</i> 10^9/L	
Dec-03-2020 10:14:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 611 Test:: Lymphocytes_PX611 Result:: 1.84 Not Done:: Lab Normal Range: <i>Low</i> 1.00 <i>High</i> 4.80	Transcription Error
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 611 Test:: Lymphocytes_PX611 Result:: 25 Not Done:: Lab Normal Range: <i>Low</i> 20 <i>High</i> 40 <i>Unit</i> %	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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5.j Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 611	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Lymphocytes_PX611	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Dec-09-2020 04:37:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-08-2020 10:12:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Answer Auto Query
Dec-04-2020 02:11:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2: Reissued: Opened	DM: Result is present. However, unit is missing. Please review and update the data. Kindly connect with CRA for any further assistance if needed.
Dec-03-2020 14:41:33 (UTC-06:00)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_LB001_08

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Central Time (US & Canada)				
Dec-03-2020 10:14:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	NO UNIT IS GIVEN IN MEDICAL RECORDS
Dec-03-2020 10:14:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-03-2020 10:14:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-03-2020 10:14:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1.84	Transcription Error
Dec-03-2020 02:21:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6299287;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 25	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.j LNMT

Date	Location	User	Value	Reason
Dec-08-2020 10:12:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: <i>Low</i> 1.00 <i>High</i> 4.80 <i>Unit</i> 10^9/L	Transcription Error
Dec-03-2020 10:14:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 1.00 <i>High</i> 4.80	Transcription Error
Dec-02-2020 13:12:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 20 <i>High</i> 40 <i>Unit</i> %	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Lab Panel:

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HEMATOLOGY	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Dec-09-2020 03:04:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-08-2020 08:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-08-2020 08:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: MOBILE INFIRMARY MEDICAL CLINIC LAB, 5 MOBILE INFIRMARY CIRCLE, MOBILE, AL	Transcription Error
Dec-06-2020 13:34:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Opened	DM :A carriage return is identified, please do not press enter key, just type lab name all in single line with comma separated.
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MOBILE INFIRMARY MEDICAL CLINIC LAB 5 MOBILE INFIRMARY CIRCLE MOBILE, AL	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
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090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1107**Site Name:** (1107) Coastal Clinical Research**Subject No:** 11071031**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49

Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/30/2020	Initial Entry
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4. Specimen Type:

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id 1 entifier: Test:: Hemoglobin _PX1 Result:: 10.0 Not Done:: Lab Normal Range <i>Low</i> : 12.0 <i>High</i> 14.0 <i>Unit</i> g/dL	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hemoglobin_PX1	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Time (US & Canada)				
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5.a Result:

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 10.0	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 12.0 <i>High</i> 14.0 <i>Unit</i> g/dL	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Hematocrit_ PX2 Result:: 32 Not Done:: Lab Normal Range: <i>Low</i> 36 <i>High</i> 48 <i>Unit</i> %	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.b Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hematocrit_PX2	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 32	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 36 <i>High</i> 48 <i>Unit</i> %	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id 3 entifier: Test:: Erythrocytes_PX3	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Result:: 3.96	
			Not Done::	
			Lab Normal Range <i>Low</i>	
			:	4.20
				<i>High</i>
				5.40
			<i>Unit</i>	
				10 ⁶ /cu m
				m

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1107**Site Name:** (1107) Coastal Clinical Research**Subject No:** 11071031**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Erythrocytes_PX3	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3.96	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 4.20 <i>High</i> 5.40 <i>Unit</i> 10 ⁶ /cu mm	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 5 Test:: Platelets_P X5	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Result:: 326	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			140	
			<i>High</i>	
			450	
			<i>Unit</i>	
			10 ³ /uL	

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1107**Site Name:** (1107) Coastal Clinical Research**Subject No:** 11071031**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Platelets_PX5	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 326	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 140 <i>High</i> 450 <i>Unit</i> 10 ³ /uL	Initial Entry

5.e

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id 7 entifier: Test:: Leukocytes_ PX7	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Result:: 6.4	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			5.0	
			<i>High</i>	
			10.0	
			<i>Unit</i>	
			10 ³ /uL	

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1107**Site Name:** (1107) Coastal Clinical Research**Subject No:** 11071031**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:49**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Leukocytes_PX7	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 6.4	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 5.0 <i>High</i> 10.0 <i>Unit</i> 10 ³ /uL	Initial Entry

5.f

Date	Location	User	Value	Reason
Dec-08-2020 10:08:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sponsor-Defined Identifier: 608 Test:: Neutrophils_ PX608	Transcription Error

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Result:: 4.22 Not Done:: Lab Normal Range: <i>Low</i> 1.80 <i>High</i> 7.00 <i>Unit</i> 10 ⁹ /L	
Dec-03-2020 10:15:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 608 Test:: Neutrophils_PX608 Result:: 4.22 Not Done:: Lab Normal Range: <i>Low</i> 1.80 <i>High</i> 7.00	Transcription Error
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 608 Test:: Neutrophils_PX608 Result:: 66 Not Done:: Lab Normal Range: <i>Low</i> 35 <i>High</i> 90 <i>Unit</i> %	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.f Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 608	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Neutrophils_PX608	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Dec-09-2020 00:20:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-08-2020 10:08:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Answer Auto Query
Dec-04-2020 02:10:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Reissued: Opened	DM: Neutrophils, Eosinophils, Monocytes, Basophils and Lymphocytes should be entered as absolute values using 10^9/L as units. Please review and confirm or clarify
Dec-03-2020 14:41:33 (UTC-06:00) Central Time	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_LB001_08

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

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(US & Canada)				
Dec-03-2020 10:18:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	NO UNIT IS GIVEN IN MEDICAL RECORDS
Dec-03-2020 10:15:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-03-2020 10:15:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-03-2020 10:15:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4.22	Transcription Error
Dec-03-2020 02:21:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6299283;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 66	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.f LNMT

Date	Location	User	Value	Reason
Dec-08-2020 10:08:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: <i>Low</i> 1.80 <i>High</i> 7.00 <i>Unit</i> 10^9/L	Transcription Error
Dec-03-2020 10:15:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 1.80 <i>High</i> 7.00	Transcription Error
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 35 <i>High</i> 90 <i>Unit</i> %	Initial Entry

5.g

Date	Location	User	Value	Reason
Dec-03-2020 10:17:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 609 Test:: Eosinophils_ PX609 Result:: 0.11 Not Done::	Transcription Error

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Header Text: c4591001

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Form Status: Data Complete, Frozen, Verified

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Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Lab Normal Range: <i>Low</i> 0.00 <i>High</i> 0.70	
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 609 Test:: Eosinophils_ PX609 Result:: 2 Not Done:: Lab Normal Range: <i>Low</i> 0 <i>High</i> 8 <i>Unit</i> %	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.g Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 609	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Eosinophils_PX609	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Dec-04-2020 02:11:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2: C losed	Open query present to update unit
Dec-03-2020 14:41:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: C losed	Auto closed by Validation Check: VC_LB001_08
Dec-03-2020 10:18:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: A nswered	NO UNIT IS GIVEN IN MEDICAL RECORDS

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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5.g Result:

Date	Location	User	Value	Reason
Dec-03-2020 10:17:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-03-2020 10:17:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-03-2020 10:17:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : 0.11	Transcription Error
Dec-03-2020 02:21:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6299284;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : 2	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
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090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Site Name: (1107) Coastal Clinical Research

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Dec-03-2020 10:17:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.00 <i>High</i> 0.70	Transcription Error
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0 <i>High</i> 8 <i>Unit</i> %	Initial Entry

5.h

Date	Location	User	Value	Reason
Dec-08-2020 10:08:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sponsor-Defined Identifier: Test:: Monocytes_ PX612 Result:: 0.72 Not Done:: Lab Normal Range: <i>Low</i> 0.00 <i>High</i> 0.80 <i>Unit</i> 10^9/L	Transcription Error
Dec-03-2020 10:17:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Monocytes_ PX612 Result:: 0.72	Transcription Error

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

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			Not Done:: Lab Normal Range: <i>Low</i> 0.00 <i>High</i> 0.80	
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 612 Test:: Monocytes_ PX612 Result:: 11 Not Done:: Lab Normal Range: <i>Low</i> 0 <i>High</i> 14 <i>Unit</i> %	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.h Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 612	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Monocytes_PX612	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Dec-09-2020 04:38:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-08-2020 10:08:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Answer Auto Query
Dec-04-2020 05:09:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	DM: Per section 8.39.4 of CRF completion guidelines, Neutrophils, Eosinophils, Monocytes, Basophils and Lymphocytes should be entered as absolute values using 10 ⁹ /L as units. Please review and update data as per available CRF

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

				options. Else clarify.
Dec-03-2020 14:41:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_LB001_08
Dec-03-2020 10:18:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	NO UNIT IS GIVEN IN MEDICAL RECORDS
Dec-03-2020 10:17:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-03-2020 10:17:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-03-2020 10:17:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.72	Transcription Error
Dec-03-2020 02:21:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6299298;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Dec-02-2020 13:15:48	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Form Version: 10-Oct-2020 16:02

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Site No: 1107

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

(UTC-06:00) Central Time (US & Canada)			11	
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5.h LNMT

Date	Location	User	Value	Reason
Dec-08-2020 10:08:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: <i>Low</i> 0.00 <i>High</i> 0.80 <i>Unit</i> 10^9/L	Transcription Error
Dec-03-2020 10:17:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.00 <i>High</i> 0.80	Transcription Error
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0 <i>High</i> 14 <i>Unit</i> %	Initial Entry

5.i

Date	Location	User	Value	Reason
Dec-08-2020 10:08:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sponsor-Defined 610 Identifier: Test:: Basophils_P X610	Transcription Error

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Site Name: (1107) Coastal Clinical Research

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Result:: 0.02 Not Done:: Lab Normal Range: <i>Low</i> 0.00 <i>High</i> 0.20 <i>Unit</i> 10^9/L	
Dec-03-2020 10:17:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 610 Test:: Basophils_P X610 Result:: 0.02 Not Done:: Lab Normal Range: <i>Low</i> 0.00 <i>High</i> 0.20	Transcription Error
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 610 Test:: Basophils_P X610 Result:: 0 Not Done:: Lab Normal Range: <i>Low</i> 0 <i>High</i> 2 <i>Unit</i> %	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.i Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 610	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Basophils_PX610	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Dec-09-2020 06:40:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Closed	Response satisfies query
Dec-08-2020 10:08:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Answer Auto Query
Dec-04-2020 05:09:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	DM: Per section 8.39.4 of CRF completion guidelines, Neutrophils, Eosinophils, Monocytes, Basophils and Lymphocytes should be entered as absolute values using 10 ⁹ /L as units. Please review and update data as per available CRF

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

				options. Else clarify.
Dec-03-2020 14:41:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_LB001_08
Dec-03-2020 10:19:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	NO UNIT IS GIVEN IN MEDICAL RECORDS
Dec-03-2020 10:17:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-03-2020 10:17:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-03-2020 10:17:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.02	Transcription Error
Dec-03-2020 02:21:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6299279;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Dec-02-2020 13:15:48	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

(UTC-06:00) Central Time (US & Canada)			0	
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5.i LNMT

Date	Location	User	Value	Reason
Dec-08-2020 10:08:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: <i>Low</i> 0.00 <i>High</i> 0.20 <i>Unit</i> 10^9/L	Transcription Error
Dec-03-2020 10:17:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.00 <i>High</i> 0.20	Transcription Error
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0 <i>High</i> 2 <i>Unit</i> %	Initial Entry

5.j

Date	Location	User	Value	Reason
Dec-08-2020 10:08:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sponsor-Defined 611 Identifier: Test:: Lymphocytes _PX611	Transcription Error

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

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Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

			Result:: 1.24 Not Done:: Lab Normal Range: <i>Low</i> 1.00 <i>High</i> 4.80 <i>Unit</i> 10 ⁹ /L	
Dec-03-2020 10:18:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 611 Test:: Lymphocytes_PX611 Result:: 1.24 Not Done:: Lab Normal Range: <i>Low</i> 1.00 <i>High</i> 4.80	Transcription Error
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 611 Test:: Lymphocytes_PX611 Result:: 20 Not Done:: Lab Normal Range: <i>Low</i> 20 <i>High</i> 40 <i>Unit</i> %	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.j Sponsor ID:

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 611	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Lymphocytes_PX611	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Dec-09-2020 06:39:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2: Closed	Response satisfies query
Dec-08-2020 10:08:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Answer Auto Query

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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5.j Result:

Date	Location	User	Value	Reason
Dec-04-2020 05:07:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued Opened	DM: Per section 8.39.4 of CRF completion guidelines, Neutrophils, Eosinophils, Monocytes, Basophils and Lymphocytes should be entered as absolute values using 10 ⁹ /L as units. Please review and update data as per available CRF options. Else clarify.
Dec-03-2020 14:41:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_LB001_08
Dec-03-2020 10:19:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	NO UNIT IS GIVEN IN MEDICAL RECORDS
Dec-03-2020 10:18:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-03-2020 10:18:23 (UTC-06:00) Central Time (US &	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Canada)				
Dec-03-2020 10:18:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : 1.24	Transcription Error
Dec-03-2020 02:21:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6299288;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : 20	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Dec-08-2020 10:08:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: <i>Low</i> 1.00 <i>High</i> 4.80 <i>Unit</i> 10^9/L	Transcription Error
Dec-03-2020 10:18:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 1.00 <i>High</i> 4.80	Transcription Error

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Dec-02-2020 13:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 20 <i>High</i> 40 <i>Unit</i> %	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Nov/29/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Date:

Date	Location	User	Value	Reason
Nov-30-2020 13:32:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-30-2020 13:32:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Record Identifier:: Not Applicable Systolic:: Not Applicable Diastolic:: Not Applicable Respiratory Rate in r espirations/minute: Not Applicable Heart Rate in beats/ minute: Not Applicable	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-30-2020 13:32:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Nov-30-2020 13:32:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
on Nov/29/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Nov-30-2020 13:32:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry
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2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Nov-30-2020 13:32:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Nov-30-2020 13:32:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

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1. Date:

Date	Location	User	Value	Reason
Nov-30-2020 13:33:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-30-2020 13:33:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Record Identifier: Not Applicable Oxygen Saturation: Not Applicable	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-30-2020 13:33:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Nov-30-2020 13:33:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History on Nov/29/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Date Time of Assessment:

Date	Location	User	Value	Reason
Nov-30-2020 13:33:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Nov-30-2020 13:33:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Nov-30-2020 13:33:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Nov-30-2020 13:33:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Nov-30-2020 13:33:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Nov-30-2020 13:33:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Nov-30-2020 13:33:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Nov-30-2020 13:33:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/29/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

Date	Location	User	Value	Reason
Nov-30-2020 13:33:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Audit Trail
on Nov/29/2020

Form Version: 06-Jul-2020 21:53

Form Status:

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Dec-02-2020 10:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: IMAGING - eCRF Audit Trail History on Nov/29/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Date of Assessment:

Date	Location	User	Value	Reason
Dec-02-2020 10:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/30/2020	Initial Entry
Dec-02-2020 10:50:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:34:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Dec-02-2020 10:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER <i>If other, specify:</i> ABDOMEN/PELVIS	Initial Entry
Dec-02-2020 10:50:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:34:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Dec-02-2020 10:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CT SCAN	Initial Entry
Dec-02-2020 10:50:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:34:11	ACV0PFEINFP6000	(b)(4),(b)(6)	Data Entry:	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - eCRF Audit Trail History
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Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

(UTC-06:00) Central Time (US & Canada)		(b)(4),(b)(6)	Not Applicable
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4. Assessment:

Date	Location	User	Value	Reason
Dec-04-2020 03:35:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Closed	Response satisfies query
Dec-03-2020 09:57:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This was the diagnosis for the Potential COVID illness, we were told not to add these as AEs
Dec-03-2020 01:24:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Opened	DM: Please confirm if the Abnormality found should be recorded as an Adverse Event, Thank you.
Dec-02-2020 10:52:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ABNORMAL <i>If abnormal, specify findings:</i> INFLAMMATORY CHANGES IN THE RIGHT COLON CONSISTENT WITH COLITIS	Initial Entry
Dec-02-2020 10:50:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Nov-30-2020 13:34:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Jan/04/2021

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: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-05-2021 07:05:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Jan/4/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Jan-05-2021 07:05:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: COVID_A1	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled
Visit on Jan/04/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1107**Subject No:** 11071031**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1107) Coastal Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:49[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-05-2021 09:07:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-05-2021 09:07:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-05-2021 09:08:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-05-2021 09:07:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-05-2021 09:07:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: YES Date of Collection: Jan/4/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-05-2021 09:08:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BNWX9F	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Jan/04/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

5.a Sample ID

Date	Location	User	Value	Reason
Jan-05-2021 09:08:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BNWX9F	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-05-2021 09:08:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BNWX9S	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-05-2021 09:08:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BNWX9S	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-05-2021 09:08:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Sample ID: BPYF3F	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-05-2021 09:08:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: BPYF3F	Initial Entry

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Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-13-2020 08:00:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Oct/12/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-13-2020 08:00:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-13-2020 08:00:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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Date	Location	User	Value	Reason
Dec-18-2020 09:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Category:

Date	Location	User	Value	Reason
Dec-18-2020 09:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-18-2020 09:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-02-2021 20:14:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-02-2021 20:14:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Jan-25-2021 15:24:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Will submit updated SAE tomorrow
Jan-25-2021 15:23:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Will submit updated SAE tomorrow
Jan-22-2021 14:50:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	Clinical Please submit a SAE followup with Gastroenterology followup, including whether a Dx is made and if subject remains on mesalamine

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Header Text: c4591001

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Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

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Jan-22-2021 10:58:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Candidate	Clinical Please submit a SAE followup with Gastroenterology followup, including whether a Dx is made and if subject remains on mesalamine
Jan-22-2021 10:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	CLINICAL Thanks; SAE report says the result of 'inflammation' for subject's 30Nov20 colonoscopy was reported by subject. Please update with Med Records report of colonoscopy, including any biopsy.
Jan-20-2021 10:41:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	abd pain removed from SAE report
Jan-20-2021 10:41:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	one SAE term deleted; 1 remains
Jan-06-2021 15:25:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASCENDING COLITIS	Changed Information
Jan-05-2021 15:05:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Waiting on further medical records to confirm if abdominal pain was considered a symptom of the colitis, if it was we will amend the term to be only ascending colitis.
Jan-05-2021 15:05:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Waiting on further medical records to confirm if abdominal pain was considered

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Subject No: 11071031

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

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				a symptom of the colitis, if it was we will amend the term to be only ascending colitis.
Jan-05-2021 14:57:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Subject reported today that test results are in, we have faxed for medical records and will update SAE form once we receive.
Dec-21-2020 08:39:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Clinical SAE report states Infectious colitis was considered/treated; please submit clinical info in a SAE update with max Temp & relevant labs (CBC/diff, stool for blood / cultures / other tests, any immune tests for non-infectious colitis)
Dec-21-2020 08:34:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical - Abd pain is a reported SAE event; however, narrative does not mention abd pain. Please provide clinical information on this SAE including location, correlation with diarrhea, duration.
Dec-20-2020 21:36:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL Please split the terms for separate reporting, on AE CRF and in the SAE report.
Dec-18-2020 09:56:53	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry

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Header Text: c4591001

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Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

(UTC-06:00) Central Time (US & Canada)

(b) (4), (b) (6)

ACUTE ABDOMINAL PAIN/ASCENDING COLITIS

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-18-2020 09:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/25/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-18-2020 09:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Dec/13/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-18-2020 09:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Dec-22-2020 06:10:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-18-2020 09:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE ACUTE ABDOMINAL PAIN/ASCENDING COLITIS: Response to "Is the adverse

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

				event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-18-2020 09:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry: YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Dec-18-2020 09:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry: NO</p>	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-02-2021 20:07:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Closed	Response satisfies query
Jan-25-2021 13:00:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Mobic is listed as a "possible" cause for the event, there has never been an actual diagnosis made.
Jan-22-2021 10:57:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Opened	CLINICAL 'Other' relationship is Unknown; however, SAE report states suspect drug MOBIC (discontinued 27Nov20) for causing the event Ascending Colitis. Please review 'Other' & update if appropriate
Dec-18-2020 09:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatme nt(s), this event is due to: OTHER <i>If Other, specify:</i> UNKNOWN	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-18-2020 09:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

Date	Location	User	Value	Reason
Dec-18-2020 09:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-18-2020 09:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Dec-18-2020 09:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Dec-18-2020 09:56:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Dec-22-2020 06:10:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Data Entry: 2020503632	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

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: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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Date	Location	User	Value	Reason
Sep-17-2020 12:12:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Form Created	

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: Data Complete, Locked, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Sep-17-2020 12:12:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Sep-17-2020 12:12:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Sep-17-2020 12:12:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	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
Sep-17-2020 12:12:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: INFLUENZA VACCINE	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Sep-17-2020 12:12:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Aug/20/2020	Initial Entry

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Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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I. Date of Visit

Date	Location	User	Value	Reason
Mar-01-2021 07:19:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Jan/7/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Mar-01-2021 07:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-01-2021 07:19:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Mar-01-2021 07:19:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Participant is willing to return f or Vaccination 3 Participant is: eligible and NOT confirmed to have received only placeb o at Vaccination 1/2	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Mar-01-2021 07:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: Jan/7/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Mar-01-2021 07:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: ASSESS ELIGIBILITY FOR A DDITIONAL VACCINATION	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1107

Subject No: 11071031

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1107) Coastal Clinical Research

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:49

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1. Subject Status

Date	Location	User	Value	Reason
Oct-13-2020 08:00:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-04-2020 16:45:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-04-2020 16:40:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-13-2020 08:00:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/12/2020	Initial Entry
Aug-04-2020 16:45:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/4/2020	Initial Entry
Aug-04-2020 16:40:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/4/2020	Initial Entry

090177e196ae3dff\Final\Final On: 01-Apr-2021 04:42 (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: 1107

Site Name: (1107) Coastal Clinical Research

Subject No: 11071031

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:49

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1. Casebook Signature

Date	Location	User	Value	Reason
Sep-09-2020 15:42:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Data Entry: Click Here to Enable	Initial Entry