

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Cohort Selection

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

1.	Select appropriate response - Protocol version	06 OCT 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Dec/7/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10091294]
2.	Birth Date:	(b) (6) 2005
3.	Sex:	FEMALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Dec/7/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable _____
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Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable _____
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090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Dec/7/2020
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: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[dermatitis, atopic]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[acne, generalized]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[menorrhagia]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

HIV Status

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Dec/7/2020
2.	Weight:	[113.4]
3.	Unit:	LB
4.	Height:	[67.0]
5.	Unit:	in
6.	Body Mass Index:	[17.8]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[99.0]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 15:58

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Dec/7/2020
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:	

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Dec/7/2020
2.	Randomization Number:	[21177]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/7/2020
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	[BR9FWD]
5.b	Sample ID	[BR9FWF]
5.c	Sample ID	[BSJ3K5]

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Dec/7/2020
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	[BGH00K]
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090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Dec/7/2020 11:38
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

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

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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
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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:27

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Vital Signs

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

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 15:58

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Dec/28/2020
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:	

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Dec/28/2020
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	[BGH04D]
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Dec/28/2020 09:36
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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT

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

Site No: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Jan/25/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Oct-2020 16:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Oct-2020 16:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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
2.g	Symptom:	NEW OR WORSENERD MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERD JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Oct-2020 16:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (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: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/25/2021
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	[BR61SH]
5.b	Sample ID	[BR61SJ]
5.c	Sample ID	[BSJ3V3]

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/16/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A
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090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form Version: 20-Feb-2021 02:17

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Mar/16/2021
2.	Date of First Symptom Started:	Mar/14/2021
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Mar/18/2021

Symptoms

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	YES
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO
Symptoms - Other		
5.	Symptoms - Other Text:	[]

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Microbiology Specimen

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Mar/16/2021
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	[RR12143]
-----	-----------	-----------

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Health Care Utilization

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Health Care Utilization Other

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

Health Care Utilization

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Respiratory Treatment

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Illness Details

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 10-Oct-2020 15:58

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 10-Oct-2020 15:58

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Lab Chemistry Details

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 10-Oct-2020 16:02

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 10-Oct-2020 16:02

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Laboratory Data Hematology

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 10-Oct-2020 15:59

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Date:	Vital Signs Details			Form Instance
1.		Record Identifier:	Systolic:	Diastolic:	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: VITAL SIGNS - COVID

Form Version: 10-Oct-2020 15:59

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Vital Signs

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

Vital Signs Details

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 10-Oct-2020 16:04

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Date:	Vital Signs Details		Form Instance
1.		Record Identifier:	Oxygen Saturation	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 10-Oct-2020 16:04

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Oxygenation Parameters

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form Version: 06-Jul-2020 21:55

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Status: Not Started

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Concomitant Medications

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Imaging

1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jun/25/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form Version: 30-Apr-2021 01:47

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Status: Data Complete

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Jun/25/2021
2.	Date of First Symptom Started:	Jun/22/2021
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Jul/1/2021

Symptoms

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	YES
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO
Symptoms - Other		
5.	Symptoms - Other Text:	[]

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Microbiology Specimen

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Jun/25/2021
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	[RR26524]
-----	-----------	-----------

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: HEALTH CARE UTILIZATION

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Health Care Utilization

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: HEALTH CARE UTILIZATION

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Health Care Utilization Other

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

Health Care Utilization

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Respiratory Treatment

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form Version: 06-Jul-2020 21:52

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: ILLNESS DETAILS

Form Status: Data Complete

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Illness Details

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 10-Oct-2020 15:58

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 10-Oct-2020 15:58

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Lab Chemistry Details

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 10-Oct-2020 16:02

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 10-Oct-2020 16:02

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Laboratory Data Hematology

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - COVID

Form Version: 10-Oct-2020 15:59

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Date:	Vital Signs Details			Form Instance
1.		Record Identifier:	Systolic:	Diastolic:	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: VITAL SIGNS - COVID

Form Version: 10-Oct-2020 15:59

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Vital Signs

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

Vital Signs Details

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 10-Oct-2020 16:04

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Date:	Vital Signs Details		Form Instance
1.		Record Identifier:	Oxygen Saturation	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 10-Oct-2020 16:04

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Oxygenation Parameters

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

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form Version: 06-Jul-2020 21:55

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Status: Not Started

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Concomitant Medications

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Imaging

1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jul/27/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Jul/27/2021
2.	Date of First Symptom Started:	Jul/23/2021
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Jul/24/2021

Symptoms

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL
COVID-19

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	YES
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO
Symptoms - Other		
5.a	Symptoms - Other Text:	[stomach ache]

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

Microbiology Specimen

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB SELF

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Jul/27/2021
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	[RR23551]
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Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form: ELECTRONIC SAMPLE TRACKING - NASAL
SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form: HEALTH CARE UTILIZATION

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Health Care Utilization

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form: HEALTH CARE UTILIZATION

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Health Care Utilization Other

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

Health Care Utilization

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Respiratory Treatment

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form Version: 06-Jul-2020 21:52

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: ILLNESS DETAILS

Form Status: Data Complete

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 3

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 3

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 10-Oct-2020 15:58

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form: LOCAL LABORATORY DATA - REPEATING
CHEMISTRY

Form Version: 10-Oct-2020 15:58

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Lab Chemistry Details

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 10-Oct-2020 16:02

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form: LOCAL LABORATORY DATA - REPEATING
Hematology

Form Version: 10-Oct-2020 16:02

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Laboratory Data Hematology

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3

Form: VITAL SIGNS - COVID

Form Version: 10-Oct-2020 15:59

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Date:	Vital Signs Details			Form Instance
1.		Record Identifier:	Systolic:	Diastolic:	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form: VITAL SIGNS - COVID

Form Version: 10-Oct-2020 15:59

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Vital Signs

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

Vital Signs Details

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 10-Oct-2020 16:04

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Date:	Vital Signs Details		Form Instance
1.		Record Identifier:	Oxygen Saturation	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 10-Oct-2020 16:04

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: c4591001

Visit: POT_COVID_ILL 3

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Oxygenation Parameters

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form Version: 06-Jul-2020 21:55

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS -
VASOPRESSORS

Form Status: Not Started

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Concomitant Medications

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					Repeating Pages

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Imaging

1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Apr/14/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Apr/14/2021
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 Apr/14/2021

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Apr/14/2021
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	[BR9DP8]
5.b	Sample ID	[BR9DP9]
5.c	Sample ID	[BSJ448]
5.d	Sample ID	[BSJ449]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB **Form:** DATE OF VISIT - REPEAT SWAB
- New Unscheduled Visit

Form Version: 10-Oct-2020 15:57 **Form Status:** Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

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:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091294**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44**Electronic Sample Tracking**

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Unplanned - New Unscheduled **Form:** DATE OF VISIT
Visit

Form Version: 22-Apr-2020 21:02 **Form Status:** Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit **Form:** UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04 **Form Status:** Not Started

Site No: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

Unplanned Assessments

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 30-Apr-2021 01:41

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family
Clinic South**Subject No:** 10091294**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44**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:	

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Vaccination

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (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: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Contact Outcome

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Contact Outcome

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT

Form Version: 10-Dec-2020 02:29 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Jan/25/2021
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT
Unscheduled

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION
Unscheduled

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Disposition - Follow-Up

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

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	bilateral shoulder pain	Dec/22/2020 UNK:UNK	NO End Date Time: Dec/24/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	body aches	Apr/6/2021 18:00	NO End Date Time: Apr/7/2021 UNK:UNK	Repeating Pages

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[bilateral shoulder pain]
4.	Start Date Time:	Dec/22/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/24/2020 UNK:UNK
6.	Toxicity Grade:	1

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [lifting heavy object]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

11.	Was a Concomitant Medication given?	NO
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	[]

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[body aches]
4.	Start Date Time:	Apr/6/2021 18:00
5.	Is the adverse event still ongoing?	NO End Date Time: Apr/7/2021 UNK:UNK
6.	Toxicity Grade:	1

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091294

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Form Status: Data Complete, Frozen

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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	[]

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Medication Error

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Concomitant Medications

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Concomitant Medications

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Radiation Treatment

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Apr/2/2021
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: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V101_VAX3

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Apr/6/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Apr/6/2021
----	--------------	---

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 28-Mar-2021 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation /Death :	Apr/6/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 28-Mar-2021 02:27

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Apr/6/2021
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:	

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Apr/6/2021
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	[BR9DN3]
5.b	Sample ID	[BSJ43Z]
5.c	Sample ID	[BRTSP1]

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Apr/6/2021
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	[BR9DT8]
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090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Apr/6/2021 09:22
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

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

Header Text: c4591001

Visit: V102_VAX4

Form Version: 28-Mar-2021 02:27

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Apr/28/2021
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:	

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Apr/28/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR9DRH]
-----	-----------	----------

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Apr/28/2021 09:35
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

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

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Contact Outcome

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Jun/1/2021
3.	Comments:	[]

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

Contact Outcome

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

Contact Outcome

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

Header Text: c4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Jun/1/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Jan/25/2021

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA -
Comments

Form Version: 10-Oct-2020 16:00

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
Form	Dec-07-2020 12:34:03 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-16-2021 15:53:05 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
1	Mar-16-2021 15:53:05 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
2	Mar-16-2021 15:53:05 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
3	Mar-16-2021 15:53:05 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

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Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

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Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
4	Mar-16-2021 15:53:05 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
5	Mar-16-2021 15:53:05 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1009

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Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
6	Mar-16-2021 15:53:05 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

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Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
7	Mar-16-2021 15:53:05 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

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Clinic South

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
8	Mar-16-2021 15:53:05 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1009

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Subject No: 10091294

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Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
9	Mar-16-2021 15:53:05 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
Form	Jun-28-2021 11:55:28 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
1	Jun-28-2021 11:55:28 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

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Form Version: 06-Jul-2020 21:54

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Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
2	Jun-28-2021 11:55:28 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form Version: 06-Jul-2020 21:54

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Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
3	Jun-28-2021 11:55:28 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

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Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
4	Jun-28-2021 11:55:28 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
5	Jun-28-2021 11:55:28 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
6	Jun-28-2021 11:55:28 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1009

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Clinic South

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
7	Jun-28-2021 11:55:28 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
8	Jun-28-2021 11:55:28 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
9	Jun-28-2021 11:55:28 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
Form	Jun-28-2021 11:58:43 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
1	Jun-28-2021 11:58:43 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
2	Jun-28-2021 11:58:43 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

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Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
3	Jun-28-2021 11:58:43 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

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Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
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Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
4	Jun-28-2021 11:58:43 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

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Form Version: 06-Jul-2020 21:53

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Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
5	Jun-28-2021 11:58:43 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

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Form Version: 06-Jul-2020 21:53

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Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
6	Jun-28-2021 11:58:43 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
Form	Jun-28-2021 11:59:33 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete

Site No: 1009

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Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
1	Jun-28-2021 11:59:33 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete

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[Back to Form](#)

Item	Date	User	Comment
2	Jun-28-2021 11:59:33 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: ILLNESS DETAILS - SEVERE - Comments

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[Back to Form](#)

Item	Date	User	Comment
3	Jun-28-2021 11:59:33 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

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Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
4	Jun-28-2021 11:59:33 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
Form	Jul-28-2021 09:17:09 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

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Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
1	Jul-28-2021 09:17:09 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

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Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
2	Jul-28-2021 09:17:09 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

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Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

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Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
4	Jul-28-2021 09:17:09 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
5	Jul-28-2021 09:17:09 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
6	Jul-28-2021 09:17:09 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
7	Jul-28-2021 09:17:09 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
8	Jul-28-2021 09:17:09 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
9	Jul-28-2021 09:17:09 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 28-Mar-2021 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Item	Date	User	Comment
Form	Apr-06-2021 12:05:56 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Apr-14-2021 09:45:18 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

(b) (6)	Approved	Apr-13-2021 18:30:54 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Apr-12-2021 14:48:36 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Affidavit:

N/A

(b) (6)	Approved	Apr-06-2021 19:22:41 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Apr-06-2021 12:04:49 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Mar-18-2021 18:59:59 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Affidavit:

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

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

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

(b) (6)	N/A	Mar-18-2021 12:26:07 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Mar-16-2021 18:16:34 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Affidavit:

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

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

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

(b) (6)	N/A	Mar-16-2021 15:51:49 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6)	Approved	Mar-13-2021 16:59:33 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - Signature
History

Form Status: Data Complete, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

Affidavit:

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

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

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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Dec-07-2020 12:33:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 06 OCT 2020	Initial Entry

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

Date	Location	User	Value	Reason
Dec-07-2020 12:33:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Dec-07-2020 12:33:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Dec/7/2020	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Dec-07-2020 12:32:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 10091294	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Dec-07-2020 12:32:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: (b) (6) 2005	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Dec-07-2020 12:33:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
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090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Dec-07-2020 12:33:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: HISPANIC OR LATINO(A) OR OF SPANISH ORIGI N	Initial Entry
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5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Dec-07-2020 12:33:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Dec-07-2020 12:33:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Dec/7/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Dec-07-2020 12:34:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Dec/7/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-07-2020 12:34:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-07-2020 12:34:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091294**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 10-Nov-2021 20:44[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
Dec-07-2020 12:35:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Line/MH Number: er: Medical History Term: dermatitis, atopic Start Date: UNK/UNK/ 2018 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Dec-07-2020 12:35:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Dec-07-2020 12:35:52 (UTC-07:00) Mountain Time (US	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: dermatitis, atopic	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

& Canada)

1.a Start Date:

Date	Location	User	Value	Reason
Dec-07-2020 12:35:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Dec-07-2020 12:35:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Dec-07-2020 12:36:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Line/MH Nu 2 mber: Medical Histo acne, gene ry Term: ralized Start Date: UNK/UN K/2017 Ongoing: YES	Transcription Error

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Dec-07-2020 12:36:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: acne Start Date: UNK/UNK/2017 Ongoing: YES	Initial Entry
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090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

1.b Line/MH Number:

Date	Location	User	Value	Reason
Dec-07-2020 12:36:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Dec-07-2020 12:36:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: acne, generalized	Transcription Error
Dec-07-2020 12:36:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: acne	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Dec-07-2020 12:36:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: UNK/UNK/2017	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

I.b Ongoing:

Date	Location	User	Value	Reason
Dec-07-2020 12:36:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.c

Date	Location	User	Value	Reason
Dec-28-2020 16:35:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Line/MH Numb 3 er: Medical Histor menorrhagi y Term: a Start Date: UNK/UNK /2018 Ongoing: YES	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

I.c Line/MH Number:

Date	Location	User	Value	Reason
Dec-28-2020 16:35:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Dec-28-2020 16:35:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: menorrhagia	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Dec-28-2020 16:35:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: UNK/UNK/2018	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
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090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Dec-28-2020 16:35:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

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

Date	Location	User	Value	Reason
Dec-07-2020 12:37:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Dec-07-2020 12:37:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Dec/7/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Dec-07-2020 12:37:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 113.4	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Dec-07-2020 12:37:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: LB	Initial Entry

4. Height:

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Dec-07-2020 12:37:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 67.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Dec-07-2020 12:37:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Dec-07-2020 12:37:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 17.8	Initial Entry

7.a

Date	Location	User	Value	Reason
Dec-07-2020 12:37:47 (UTC-07:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Record Identif 1	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Mountain Time (US & Canada)			ier:: Temperature: 99.0 Temperature F Unit: Temperature ORAL CA Location:: VITY
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7.a Record Identifier:

Date	Location	User	Value	Reason
Dec-07-2020 12:37:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Dec-07-2020 12:37:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 99.0	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Dec-07-2020 12:37:47 (UTC-07:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: F	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Mountain Time (US & Canada)

7.a Temperature Location:

Date	Location	User	Value	Reason
Dec-07-2020 12:37:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Dec-07-2020 12:38:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Dec-07-2020 12:38:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Dec-07-2020 12:38:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Dec/7/2020	Initial Entry

4. Laboratory Name and Address (Derived)

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Dec-07-2020 12:38:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Dec-07-2020 12:38:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Dec-07-2020 12:38:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX 113 Result:: NEGATIVE Not Done::	Initial Entry

6.a Sponsor ID:

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Dec-07-2020 12:38:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Dec-07-2020 12:38:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_P X113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Dec-07-2020 12:38:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Dec-07-2020 12:38:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Dec/7/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Dec-07-2020 12:38:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 21177	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Dec-07-2020 12:42:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-07-2020 12:42:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-07-2020 12:42:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-07-2020 12:42:31	ACV0PF EINFP60	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (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: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00			Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-07-2020 12:42:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/7/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-07-2020 12:42:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BR9FWD	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-07-2020 12:42:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BR9FWD	Initial Entry

5.b

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (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: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Dec-07-2020 12:42:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BR9FWF	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-07-2020 12:42:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BR9FWF	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-07-2020 12:43:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BSJ3K5	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

5.c Sample ID

Date	Location	User	Value	Reason
Dec-07-2020 12:43:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	Data Entry: BSJ3K5	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (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: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Dec-07-2020 12:41:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-07-2020 12:41:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-07-2020 12:42:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-07-2020 12:41:57	ACV0PF EINFP60	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (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: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00			Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-07-2020 12:41:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/7/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-07-2020 12:42:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BGH00K	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-07-2020 12:42:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BGH00K	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Dec-07-2020 12:39:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Dec-07-2020 12:39:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Dec-07-2020 12:39:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Dec-07-2020 12:39:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Dec/7/2020 11:38	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Dec-07-2020 12:39:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Dec-07-2020 12:39:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Dec-07-2020 12:39:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Dec-07-2020 12:39:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	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
Dec-07-2020 12:39:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Dec-07-2020 12:39:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES - REACTOGENICIT Y E-DIARY COLLECTED FOR THIS SUBJECT	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Dec-28-2020 13:03:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Dec/28/2020	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

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

Date	Location	User	Value	Reason
Dec-28-2020 13:04:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Dec-28-2020 13:04:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: FE V ER Were fever or systemic N symptoms present on t O he last day the Subject Diary was completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Dec-28-2020 13:04:28 (UTC-07:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Mountain Time (US & Canada)

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

Date	Location	User	Value	Reason
Dec-28-2020 13:04:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Dec-28-2020 13:04:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI GU E Were fever or systemic symptoms present on the last day the Subject Diary was completed? NO :	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.b Symptom:

Date	Location	User	Value	Reason
Dec-28-2020 13:04:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(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
Dec-28-2020 13:04:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Dec-28-2020 13:04:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
Dec-28-2020 13:04:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(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
Dec-28-2020 13:04:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Dec-28-2020 13:04:28 (UTC-07:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: C HI	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Mountain Time (US & Canada)			LL S N O	
Were fever or systemic symptoms present on the last day the Subject Diary was completed?:				

2.d Symptom:

Date	Location	User	Value	Reason
Dec-28-2020 13:04:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 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
Dec-28-2020 13:04:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Dec-28-2020 13:04:28	ACV0PF EINFP60	(b) (4), (b) (6)	Data Entry: Symptom:: VO	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00	(b) (4), (b) (6)	MI TIN G	Were fever or systemi c symptoms present o n the last day the Sub ject Diary was comple ted?:	
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2.e Symptom:

Date	Location	User	Value	Reason
Dec-28-2020 13:04:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(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
Dec-28-2020 13:04:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
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090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Dec-28-2020 13:04:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: DI AR RH EA Were fever or systemi c symptoms present o n the last day the Subj ect Diary was complet ed?: NO	Initial Entry
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2.f Symptom:

Date	Location	User	Value	Reason
Dec-28-2020 13:04:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 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
Dec-28-2020 13:04:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Dec-28-2020 13:04:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<p>Data Entry:</p> <p>Symptom:: NEW O R WOR SENE D MUSCL E PAIN</p> <p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO</p>	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

2.g Symptom:

Date	Location	User	Value	Reason
Dec-28-2020 13:04:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD MU SCLE 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
Dec-28-2020 13:04:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Dec-28-2020 13:04:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WOR SENERD JOINT P AIN	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

			Were fever or syst NO emic symptoms p resent on the last day the Subject D iary was complete d?:	
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2.h Symptom:

Date	Location	User	Value	Reason
Dec-28-2020 13:04:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR WORSENE D JOI NT 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
Dec-28-2020 13:04:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Dec-28-2020 13:04:28	ACV0PF EINFP60	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00			
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4. Injection Site Body Side:

Date	Location	User	Value	Reason
Dec-28-2020 13:04:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-28-2020 13:04:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: RE DN ES S Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
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090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Dec-28-2020 13:04:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: REDNESS	Initial Entry
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5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Dec-28-2020 13:04:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-28-2020 13:04:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: SW ELL ING Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Dec-28-2020 13:04:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(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
Dec-28-2020 13:04:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-28-2020 13:04:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Injection Site Reaction:: PAIN AT INJECTION SITE	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
Dec-28-2020 13:04:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(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
Dec-28-2020 13:04:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:27

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Dec-28-2020 13:04:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Dec/28/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Dec-28-2020 13:04:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 98.3 Temperature Unit: F Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Dec-28-2020 13:04:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:27

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

2.a Temperature:

Date	Location	User	Value	Reason
Dec-28-2020 13:04:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 98.3	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Dec-28-2020 13:04:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Dec-28-2020 13:04:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Dec-28-2020 13:05:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Dec-28-2020 13:05:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Dec-28-2020 13:05:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Dec/28/2020	Initial Entry

4. Laboratory Name and Address (Derived)

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Dec-28-2020 13:05:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Dec-28-2020 13:05:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Dec-28-2020 13:05:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX 113 Result:: NEGATIVE Not Done::	Initial Entry

6.a Sponsor ID:

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Dec-28-2020 13:05:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Dec-28-2020 13:05:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_P X113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Dec-28-2020 13:05:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (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: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Dec-28-2020 13:05:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-28-2020 13:05:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-05-2021 11:26:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-29-2020 01:18:52	ACV0PF EINFP60	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (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: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00			Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-28-2020 13:05:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-28-2020 13:05:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/28/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-05-2021 11:26:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BGH04D	Initial Entry

5.a Sample ID

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (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: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jan-05-2021 11:26:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> BGH04D	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Dec-2020 02:26

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Dec-28-2020 13:06:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Dec-28-2020 13:06:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Dec-28-2020 13:06:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Dec-28-2020 13:06:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Dec/28/2020 09:36	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Dec-28-2020 13:06:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Dec-28-2020 13:06:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Dec-28-2020 13:06:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Dec-28-2020 13:06:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	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
Dec-28-2020 13:06:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (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: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jan-31-2021 23:35:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 1: Closed	Response satisfies query
Jan-29-2021 16:56:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	Changed data per query
Jan-27-2021 04:26:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	DM: The treatment period is defined as 1st vaccination visit through the 1-month post vaccination visit after the 2nd vaccination. Please complete treatment disposition CRF and update date of EOT to match date of visit at visit 3.

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (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: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

Jan-25-2021 12:37:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: Jan/25/2021	Initial Entry
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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

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

Date	Location	User	Value	Reason
Jan-25-2021 12:38:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-25-2021 12:38:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: FE V ER Were fever or systemic N symptoms present on t O he last day the Subject Diary was completed?:	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Jan-25-2021 12:38:20 (UTC-07:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009 Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

Mountain Time (US & Canada)				
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2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-25-2021 12:38:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Jan-25-2021 12:38:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: FA TI GU E Were fever or systemic symptoms present on the last day the Subject Diary was completed? NO : :	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

2.b Symptom:

Date	Location	User	Value	Reason
Jan-25-2021 12:38:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(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
Jan-25-2021 12:38:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Jan-25-2021 12:38:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009 Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
Jan-25-2021 12:38:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 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
Jan-25-2021 12:38:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Jan-25-2021 12:38:20 (UTC-07:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: C HI	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009 Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

Mountain Time (US & Canada)			LL S N O	
Were fever or systemic symptoms present on the last day the Subject Diary was completed?:				

2.d Symptom:

Date	Location	User	Value	Reason
Jan-25-2021 12:38:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 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
Jan-25-2021 12:38:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Jan-25-2021 12:38:20	ACV0PF EINFP60	(b) (4), (b) (6)	Data Entry: Symptom:: VO	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00	(b) (4), (b) (6)	MI TIN G Were fever or systemi c symptoms present o n the last day the Sub ject Diary was comple ted?:	
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2.e Symptom:

Date	Location	User	Value	Reason
Jan-25-2021 12:38:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(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
Jan-25-2021 12:38:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
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090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009 Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

Jan-25-2021 12:38:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: DI AR RH EA Were fever or systemi c symptoms present o n the last day the Subj ect Diary was complet ed?: NO	Initial Entry
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2.f Symptom:

Date	Location	User	Value	Reason
Jan-25-2021 12:38:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 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
Jan-25-2021 12:38:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.g

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jan-25-2021 12:38:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WOR SENED MUSCL E PAIN Were fever or sys temic symptoms present on the las t day the Subject Diary was comple ted?: NO	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009 Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

2.g Symptom:

Date	Location	User	Value	Reason
Jan-25-2021 12:38:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR WORSENERD MU SCLE 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
Jan-25-2021 12:38:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Jan-25-2021 12:38:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom:: NEW O R WOR SENERD JOINT P AIN	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009 Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

			Were fever or syst NO emic symptoms p resent on the last day the Subject D iary was complete d?:	
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2.h Symptom:

Date	Location	User	Value	Reason
Jan-25-2021 12:38:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR WORSENE D 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
Jan-25-2021 12:38:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Jan-25-2021 12:38:20 (UTC-07:00)	ACV0PF EINFP60	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009 Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

Mountain Time (US & Canada)	00			
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4. Injection Site Body Side:

Date	Location	User	Value	Reason
Jan-25-2021 12:38:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-25-2021 12:38:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction: RE DN ES S Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-25-2021 12:38:20	ACV0PF EINFP60	(b) (4), (b) (6)	<u>Data Entry:</u> REDNESS	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009 Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00	(b) (4), (b) (6)		
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5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Jan-25-2021 12:38:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-25-2021 12:38:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Injection Site Reaction: SW ELL ING Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009 Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Jan-25-2021 12:38:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Jan-25-2021 12:38:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-25-2021 12:38:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reac tion:: PAIN AT INJ ECTI ON SI TE	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03 Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009 Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

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

Date	Location	User	Value	Reason
Jan-25-2021 12:38:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(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
Jan-25-2021 12:38:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (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: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jan-25-2021 12:38:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-25-2021 12:38:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-25-2021 13:01:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-25-2021 12:38:35 (UTC-07:00) Mountain Time (US	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (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: 1009 Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 10-Nov-2021 20:44

& Canada)				entered. Please review and correct as appropriate.
Jan-25-2021 12:38:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/25/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-25-2021 13:01:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BR61SH	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 13:01:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BR61SH	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (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: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

Jan-25-2021 13:01:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BR61SJ	Initial Entry
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5.b Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 13:01:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BR61SJ	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-25-2021 13:02:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BSJ3V3	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (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: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

5.c Sample ID

Date	Location	User	Value	Reason
Jan-25-2021 13:02:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BSJ3V3	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS ONSET - eCRF
Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Mar-16-2021 15:53:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-16-2021 15:52:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Mar-16-2021 15:51:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	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.
Mar-16-2021 15:51:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: DATE OF VISIT - ILLNESS ONSET - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				Self and Nasal Swab are missing. Please review and update as appropriate.
Mar-16-2021 15:51:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Mar/16/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Mar-16-2021 15:51:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form Version: 20-Feb-2021 02:17

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Assessment:

Date	Location	User	Value	Reason
Mar-16-2021 15:52:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Mar/16/2021	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Mar-16-2021 15:52:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Mar/14/2021	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Apr-19-2021 08:09:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Apr-16-2021 15:26:28	ACV0PF EINFP60	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

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

Form Version: 20-Feb-2021 02:17

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00	(b) (4), (b) (6)		
Apr-16-2021 09:57:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Answered	Transcription Error
Apr-16-2021 09:57:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	Transcription Error
Apr-16-2021 09:57:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom R esolved: Mar/18/2021	Transcription Error
Apr-12-2021 11:54:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 2: Opened	Per source end date was 18Mar2021 please confirm and update EDC if applicable.
Apr-07-2021 11:15:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Please clarify whether the reported symptoms are

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

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

Form Version: 20-Feb-2021 02:17

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				still ongoing? If symptoms have ended, please update 'Symptoms Ongoing' on to 'NO' and add Date of Last Symptom Resolved on the CRF.
Mar-16-2021 15:52:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Mar-16-2021 15:52:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Mar-16-2021 15:52:27	ACV0PF EINFP60	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

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

Form Version: 20-Feb-2021 02:17

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00	(b) (4), (b) (6)		
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4.a Was symptom present?

Date	Location	User	Value	Reason
Mar-16-2021 15:52:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Mar-16-2021 15:52:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCR s: EASED COUGH Symptom NO Present:	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

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

Form Version: 20-Feb-2021 02:17

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

4.b Symptoms:

Date	Location	User	Value	Reason
Mar-16-2021 15:52:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED CO UGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Mar-16-2021 15:52:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Mar-16-2021 15:52:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREA oms: SED SHORTNESS OF BREATH Symptom Pre sent: NO	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form Version: 20-Feb-2021 02:17

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

4.c Symptoms:

Date	Location	User	Value	Reason
Mar-16-2021 15:52:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SH ORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Mar-16-2021 15:52:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Mar-16-2021 15:52:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: CHILL S Symptom Present YES :	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form Version: 20-Feb-2021 02:17

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

4.d Symptoms:

Date	Location	User	Value	Reason
Mar-16-2021 15:52:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Mar-16-2021 15:52:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.e

Date	Location	User	Value	Reason
Mar-16-2021 15:52:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR INCREASED MUSCLE PAIN Symptom Present: YES	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form Version: 20-Feb-2021 02:17

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

4.e Symptoms:

Date	Location	User	Value	Reason
Mar-16-2021 15:52:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MU SCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Mar-16-2021 15:52:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.f

Date	Location	User	Value	Reason
Mar-16-2021 15:52:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom: NEW LOSS OF TASTE OR SMLL Symptom Present: NO	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form Version: 20-Feb-2021 02:17

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

4.f Symptoms:

Date	Location	User	Value	Reason
Mar-16-2021 15:52:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Mar-16-2021 15:52:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Mar-16-2021 15:52:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCRE ASED SORE TH ROAT Symptom Present: YES	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

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

Form Version: 20-Feb-2021 02:17

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

4.g Symptoms:

Date	Location	User	Value	Reason
Mar-16-2021 15:52:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SO RE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Mar-16-2021 15:52:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Mar-16-2021 15:52:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHE A Symptom Present: NO nt:	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form Version: 20-Feb-2021 02:17

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

4.h Symptoms:

Date	Location	User	Value	Reason
Mar-16-2021 15:52:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Mar-16-2021 15:52:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Mar-16-2021 15:52:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITIN G Symptom Present: NO nt:	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form Version: 20-Feb-2021 02:17

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

4.i Symptoms:

Date	Location	User	Value	Reason
Mar-16-2021 15:52:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Mar-16-2021 15:52:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Actual Date of Collection:

Date	Location	User	Value	Reason
Mar-16-2021 15:53:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Mar-16-2021 15:53:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Mar-16-2021 15:53:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Assay Code and Description:

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Mar-16-2021 15:53:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Mar-16-2021 15:53:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Mar-16-2021 15:53:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Mar-16-2021 15:53:05 (UTC-07:00)	ACV0PF EINFP60 00	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Mountain Time (US
& Canada)

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Mar-16-2021 15:53:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Mar-16-2021 15:53:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Mar-16-2021 15:53:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-16-2021 15:53:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-19-2021 05:04:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Data updated.
Mar-18-2021 12:26:07	ACV0PF EINFP60	auto query (autoquery)	Query 1: Answered	Answer Auto Query

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00			
Mar-18-2021 00:04:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 1: Reissued:Opened	DM: Please let us know date when you will be able update barcode details. Thank you.
Mar-17-2021 08:39:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	not yet received
Mar-17-2021 02:23:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-16-2021 15:53:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

Mar-16-2021 15:53:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	Data Entry: YES Date of Collection: Mar/16/2021	Initial Entry
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5.a

Date	Location	User	Value	Reason
Mar-18-2021 12:26:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	Data Entry: Sample ID: RR12143	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-18-2021 12:26:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	Data Entry: RR12143	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Mar-16-2021 15:53:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-16-2021 15:53:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-16-2021 15:53:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(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:

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Mar-16-2021 15:53:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: self swab collected	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 20-Feb-2021 02:19

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1.a

Date	Location	User	Value	Reason
Mar-16-2021 15:55:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Mar-16-2021 15:55:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Mar-16-2021 15:55:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.b

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 20-Feb-2021 02:19

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Mar-16-2021 15:55:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Practitioner: EMERGE NCY ROOM M Occurrence of Visits or Contacts: NO	Initial Entry

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Mar-16-2021 15:55:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Mar-16-2021 15:55:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.c

Date	Location	User	Value	Reason
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090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 20-Feb-2021 02:19

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Mar-16-2021 15:55:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry
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1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Mar-16-2021 15:55:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Mar-16-2021 15:55:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
Mar-16-2021 15:55:35	ACV0PF EINFP60	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGENT CARE	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 20-Feb-2021 02:19

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00	(b) (4), (b) (6)	ner: T CARE Occurrence of Vi sits or Contacts: NO
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1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Mar-16-2021 15:55:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Mar-16-2021 15:55:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Mar-16-2021 15:55:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHON E CONSULT ATION	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 20-Feb-2021 02:19

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

			Occurrence of NO f Visits or Co ntacts:	
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1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Mar-16-2021 15:55:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTAT ION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Mar-16-2021 15:55:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Mar-16-2021 15:55:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTH ER Occurrence of Visits NO or Contacts:	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 20-Feb-2021 02:19

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Mar-16-2021 15:55:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Mar-16-2021 15:55:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(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
Mar-16-2021 15:55:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 -
Unscheduled Visit on Mar/16/2021

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Mar-16-2021 15:56:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILL NESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Mar-16-2021 15:56:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-16-2021 15:56:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS ONSET - eCRF
Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jun-28-2021 12:27:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Jun-28-2021 12:00:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jun/25/2021	Transcription Error
Jun-28-2021 11:59:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 3: Answered	Changed data per query
Jun-28-2021 11:55:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jun-28-2021 02:31:42 (UTC-07:00) Mountain Time (US	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 3: Opened	DM: Kindly consider to update missing COVID TEST

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: DATE OF VISIT - ILLNESS ONSET - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

& Canada)				form or else clarify. Thank you.
Jun-27-2021 22:16:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Jun-25-2021 18:09:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jun-25-2021 18:08:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	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.
Jun-25-2021	ACV0PF	auto query	Query 1: Candidate	Date of Visit is

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: DATE OF VISIT - ILLNESS ONSET - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

18:08:51 (UTC-07:00) Mountain Time (US & Canada)	EINFP60 00	(autoquery)		completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Jun-25-2021 18:08:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Jun/22/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Jun-25-2021 18:08:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: COVID_B	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form Version: 30-Apr-2021 01:47

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Assessment:

Date	Location	User	Value	Reason
Jun-28-2021 12:00:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jun-25-2021 18:09:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Opened	Date of assessment is not same as Date Visit. Please check and correct.
Jun-25-2021 18:09:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	Data Entry: Jun/25/2021	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Jun-25-2021 18:09:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	Data Entry: Jun/22/2021	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

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

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Aug-03-2021 22:58:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-03-2021 09:49:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	New Information
Aug-03-2021 09:49:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom R esolved: Jul/1/2021	New Information
Jul-29-2021 01:23:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	DM: Next visit should be entered only if all the symptoms at this visit resolved. If resolved, please review and update the date of last symptom resolved as

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

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

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				appropriate. If not, please move details from next visit into this visit. Thank you.
Jun-25-2021 18:09:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Jun-25-2021 18:09:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Jun-25-2021 18:09:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form Version: 30-Apr-2021 01:47

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jun-25-2021 18:09:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Jun-25-2021 18:09:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Symptom NEW OR INCR s: EASED COUGH Symptom YES Present:	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form Version: 30-Apr-2021 01:47

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

4.b Symptoms:

Date	Location	User	Value	Reason
Jun-25-2021 18:09:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED CO UGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Jun-25-2021 18:09:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Jun-25-2021 18:09:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR INCREA SED SHORTNESS OF BREATH Symptom Pre sent: NO	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

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

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

4.c Symptoms:

Date	Location	User	Value	Reason
Jun-25-2021 18:09:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SH ORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Jun-25-2021 18:09:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Jun-25-2021 18:09:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: CHILL S Symptom Present NO :	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form Version: 30-Apr-2021 01:47

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

4.d Symptoms:

Date	Location	User	Value	Reason
Jun-25-2021 18:09:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Jun-25-2021 18:09:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Jun-25-2021 18:09:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR INCREASED MUSCLE PAIN Symptom Present: NO	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form Version: 30-Apr-2021 01:47

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

4.e Symptoms:

Date	Location	User	Value	Reason
Jun-25-2021 18:09:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MU SCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Jun-25-2021 18:09:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Jun-25-2021 18:09:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sympto NEW LOSS OF ms: TASTE OR SME LL Sympto NO m Presen t:	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form Version: 30-Apr-2021 01:47

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

4.f Symptoms:

Date	Location	User	Value	Reason
Jun-25-2021 18:09:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Jun-25-2021 18:09:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Jun-25-2021 18:09:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR INCRE ASED SORE TH ROAT Symptom Present: YES	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form Version: 30-Apr-2021 01:47

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

4.g Symptoms:

Date	Location	User	Value	Reason
Jun-25-2021 18:09:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SO RE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Jun-25-2021 18:09:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Jun-25-2021 18:09:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHE A Symptom Prese nt: NO	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form Version: 30-Apr-2021 01:47

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

4.h Symptoms:

Date	Location	User	Value	Reason
Jun-25-2021 18:09:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Jun-25-2021 18:09:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Jun-25-2021 18:09:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITIN G Symptom Present: NO nt:	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form Version: 30-Apr-2021 01:47

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

4.i Symptoms:

Date	Location	User	Value	Reason
Jun-25-2021 18:09:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Jun-25-2021 18:09:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: NO	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form Version: 06-Jul-2020 21:54

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Status: Data Complete

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Actual Date of Collection:

Date	Location	User	Value	Reason
Jun-28-2021 11:55:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jun-28-2021 11:55:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Jun-28-2021 11:55:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Assay Code and Description:

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form Version: 06-Jul-2020 21:54

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Status: Data Complete

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jun-28-2021 11:55:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	Data Entry: Not Applicable	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Jun-28-2021 11:55:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	Data Entry: Not Applicable	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Jun-28-2021 11:55:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	Data Entry: Not Applicable	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Jun-28-2021 11:55:28 (UTC-07:00)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	Data Entry: Not Applicable	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Mountain Time (US
& Canada)

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Jun-28-2021 11:55:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Jun-28-2021 11:55:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jun-28-2021 11:55:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jun-28-2021 11:55:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jun-29-2021 08:09:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jun-28-2021 11:55:52 (UTC-07:00) Mountain Time (US	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

& Canada)				entered. Please review and correct as appropriate.
Jun-28-2021 11:55:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jun/25/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jun-29-2021 08:09:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: RR26524	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jun-29-2021 08:09:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: RR26524	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jun-28-2021 11:56:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jun-28-2021 11:56:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jun-28-2021 11:56:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jun-28-2021 11:56:04 (UTC-07:00) Mountain Time (US	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Opened	'Sample Collected?' is marked as No and 'If no

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

& Canada)				sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Jun-28-2021 11:56:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(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
Jun-28-2021 11:56:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NA	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form Version: 30-Apr-2021 01:37

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Status: Data Complete

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1.a

Date	Location	User	Value	Reason
Jun-25-2021 18:10:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jun-25-2021 18:10:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jun-25-2021 18:10:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: NO	Initial Entry

1.b

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jun-25-2021 18:10:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Type of Practitioner: EMERGE NCY ROO M Occurrence of Visits or Con- tacts: NO	Initial Entry

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jun-25-2021 18:10:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jun-25-2021 18:10:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: NO	Initial Entry

1.c

Date	Location	User	Value	Reason
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090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jun-25-2021 18:10:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry
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1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jun-25-2021 18:10:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jun-25-2021 18:10:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
Jun-25-2021 18:10:16	ACV0PF EINFP60	(b) (4), (b) (6) [Redacted]	Data Entry: Type of Practitioner: URGENT CARE	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00	(b) (4), (b) (6)	ner: T CARE Occurrence of Vi sits or Contacts: NO
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1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jun-25-2021 18:10:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jun-25-2021 18:10:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Jun-25-2021 18:10:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Pract TELEPHON itioner: E CONSULT ATION	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

			Occurrence of NO f Visits or Co ntacts:	
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1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jun-25-2021 18:10:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: TELEPHONE CONSULTAT ION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jun-25-2021 18:10:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Jun-25-2021 18:10:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Type of Practitioner: OTH ER Occurrence of Visits NO or Contacts:	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jun-25-2021 18:10:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jun-25-2021 18:10:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(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
Jun-28-2021 12:28:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jun-28-2021 11:57:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form Version: 30-Apr-2021 01:37

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Status: Data Complete

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

Jun-28-2021 11:57:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: NO	Initial Entry
Jun-28-2021 02:09:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	DM: Please complete this item. Thank you.

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form Version: 06-Jul-2020 21:53

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: RESPIRATORY TREATMENT - eCRF Audit Trail
History

Form Status: Data Complete

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Jun-28-2021 11:58:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Jun-28-2021 11:58:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Jun-28-2021 11:58:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Treatment:

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: RESPIRATORY TREATMENT - eCRF Audit Trail
History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jun-28-2021 11:58:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Jun-28-2021 11:58:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Jun-28-2021 11:58:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Jun-28-2021 11:59:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILL NESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Jun-28-2021 11:59:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Jun-28-2021 11:59:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form: ILLNESS DETAILS - SEVERE - eCRF Audit
Trail History

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Jun-28-2021 11:59:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Jun-28-2021 11:59:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Jun-28-2021 11:59:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Toxicity Grade:

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 -
Unscheduled Visit on Jun/25/2021

Form Version: 17-Jul-2020 21:55

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: ILLNESS DETAILS - SEVERE - eCRF Audit
Trail History

Form Status: Data Complete

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Jun-28-2021 11:59:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS ONSET - eCRF
Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Aug-06-2021 08:18:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-05-2021 12:51:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Jul-29-2021 22:27:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Please let us know tentative date by when you will be able to update the details. Thank you.
Jul-29-2021 08:18:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	will update once received
Jul-28-2021	ACV0PF	(b) (4), (b) (6)	Query 1: Opened	Date of Visit is

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form: DATE OF VISIT - ILLNESS ONSET - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

22:12:10 (UTC-07:00) Mountain Time (US & Canada)	EINFP60 00	(b) (4), (b) (6)		completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Jul-28-2021 09:15:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jul-28-2021 09:14:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	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.
Jul-28-2021 09:14:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form: DATE OF VISIT - ILLNESS ONSET - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				Nasal Swab are missing. Please review and update as appropriate.
Jul-28-2021 09:14:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	Data Entry: Jul/27/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Jul-28-2021 09:14:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: COVID_C	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

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

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Assessment:

Date	Location	User	Value	Reason
Jul-28-2021 09:15:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jul/27/2021	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Jul-28-2021 09:15:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jul/23/2021	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Jul-28-2021 09:15:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Res olved: Jul/24/2021	Initial Entry

4.a

Date	Location	User	Value	Reason
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090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

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

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jul-28-2021 09:15:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry
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4.a Symptoms:

Date	Location	User	Value	Reason
Jul-28-2021 09:15:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Jul-28-2021 09:15:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Jul-28-2021 09:15:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCR s: EASED COUGH Symptom NO Present:	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

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

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

4.b Symptoms:

Date	Location	User	Value	Reason
Jul-28-2021 09:15:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED CO UGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Jul-28-2021 09:15:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Jul-28-2021 09:15:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sympt NEW OR INCREA oms: SED SHORTNESS OF BREATH Sympt NO om Pre sent:	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

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

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

4.c Symptoms:

Date	Location	User	Value	Reason
Jul-28-2021 09:15:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SH ORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Jul-28-2021 09:15:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Jul-28-2021 09:15:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: CHILL S Symptom Present NO :	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

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

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

4.d Symptoms:

Date	Location	User	Value	Reason
Jul-28-2021 09:15:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Jul-28-2021 09:15:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Jul-28-2021 09:15:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom Present: NO	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

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

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

4.e Symptoms:

Date	Location	User	Value	Reason
Jul-28-2021 09:15:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MU SCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Jul-28-2021 09:15:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Jul-28-2021 09:15:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptom: NEW LOSS OF TASTE OR SME LL Symptom Present: NO	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

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

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

4.f Symptoms:

Date	Location	User	Value	Reason
Jul-28-2021 09:15:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Jul-28-2021 09:15:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Jul-28-2021 09:15:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCRE ASED SORE TH ROAT Symptom Present: YES	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form Version: 30-Apr-2021 01:47

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

4.g Symptoms:

Date	Location	User	Value	Reason
Jul-28-2021 09:15:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SO RE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Jul-28-2021 09:15:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Jul-28-2021 09:15:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHE A Symptom Prese nt: NO	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

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

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

4.h Symptoms:

Date	Location	User	Value	Reason
Jul-28-2021 09:15:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Jul-28-2021 09:15:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Jul-28-2021 09:15:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITIN G Symptom Prese nt: NO	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

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

Form Version: 30-Apr-2021 01:47

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

4.i Symptoms:

Date	Location	User	Value	Reason
Jul-28-2021 09:15:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Jul-28-2021 09:15:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Jul-28-2021 09:20:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Symptoms - Other: stomach ache	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Jul-28-2021 09:20:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: stomach ache	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Actual Date of Collection:

Date	Location	User	Value	Reason
Jul-28-2021 09:17:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jul-28-2021 09:17:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Jul-28-2021 09:17:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Jul-28-2021 09:17:09	ACV0PF	(b) (4), (b) (6)	Data Entry:	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	EINFP60 00	(b) (4), (b) (6)	Not Done	
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5. Device Type:

Date	Location	User	Value	Reason
Jul-28-2021 09:17:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Jul-28-2021 09:17:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (4), (b) (6)	Data Entry: Not Done	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Jul-28-2021 09:17:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (4), (b) (6)	Data Entry: Not Done	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
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090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form Version: 06-Jul-2020 21:54

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: MICROBIOLOGY SPECIMEN - eCRF Audit
Trail History

Form Status: Data Complete

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

Jul-28-2021 09:17:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Jul-28-2021 09:17:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jul-28-2021 09:18:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jul-28-2021 09:18:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-11-2021 02:19:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-10-2021 11:34:22 (UTC-07:00) Mountain Time (US	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	Answer Auto Query

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

& Canada)				
Aug-10-2021 11:34:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: YES Date of Collection: Jul/27/2021	Transcription Error
Aug-05-2021 13:58:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 1: Reissued:Open ed	DM1: Please add the collection date.
Aug-05-2021 12:51:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Answered	Answer Auto Query
Jul-29-2021 22:28:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 1: Reissued:Open ed	DM: Please let us know tentative date by when you will be able to update the details. Thank you.
Jul-29-2021 08:19:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	will update once received

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jul-29-2021 00:11:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jul-28-2021 09:18:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jul-28-2021 09:18:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-05-2021 12:51:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: RR23551	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

5.a Sample ID

Date	Location	User	Value	Reason
Aug-05-2021 12:51:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: RR23551	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Jul-28-2021 09:19:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jul-28-2021 09:19:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jul-28-2021 09:19:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(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
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090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

Jul-28-2021 09:19:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: self swab collected	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1.a

Date	Location	User	Value	Reason
Jul-28-2021 09:20:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jul-28-2021 09:20:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jul-28-2021 09:20:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.b

Date	Location	User	Value	Reason
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090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Jul-28-2021 09:20:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Practitioner: EMERGE NCY ROO M Occurrence of Visits or Contacts: NO	Initial Entry
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1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jul-28-2021 09:20:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jul-28-2021 09:20:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.c

Date	Location	User	Value	Reason
Jul-28-2021 09:20:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY C ARE PHYSI CIAN	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

			Occurrence of NO f Visits or Co ntacts:	
--	--	--	--	--

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jul-28-2021 09:20:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICI AN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jul-28-2021 09:20:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
Jul-28-2021 09:20:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Practitio URGEN ner: T CARE Occurrence of Vi NO sits or Contacts:	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jul-28-2021 09:20:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jul-28-2021 09:20:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Jul-28-2021 09:20:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHON E CONSULT ATION Occurrence of Visits or Co ntacts: NO	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jul-28-2021 09:20:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTAT ION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jul-28-2021 09:20:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Jul-28-2021 09:20:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTH ER Occurrence of Visits or Contacts: NO	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit
Trail History

Form Version: 30-Apr-2021 01:37

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jul-28-2021 09:20:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jul-28-2021 09:20:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(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
Jul-28-2021 09:20:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 3 -
Unscheduled Visit on Jul/27/2021

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Jul-28-2021 09:20:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILL NESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Jul-28-2021 09:20:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Jul-28-2021 09:20:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Apr/14/2021

Form Version: 22-Apr-2020 21:04

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: DATE OF VISIT - ILLNESS CONVALESCENT -
eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Apr-14-2021 09:45:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Apr/14/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Apr-14-2021 09:45:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: COVID_A1	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Apr/14/2021

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Apr-14-2021 09:45:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Apr-14-2021 09:45:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Apr-14-2021 09:49:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Apr-14-2021 09:45:34	ACV0PF EINFP60	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Apr/14/2021

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00			Yes, however no barcodes are entered. Please review and correct as appropriate.
Apr-14-2021 09:45:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Apr/14/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Apr-14-2021 09:49:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BR9DP8	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Apr-14-2021 09:49:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BR9DP8	Initial Entry

5.b

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Apr/14/2021

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Apr-14-2021 09:49:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BR9DP9	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Apr-14-2021 09:49:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BR9DP9	Initial Entry

5.c

Date	Location	User	Value	Reason
Apr-14-2021 09:49:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BSJ448	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 -
Unscheduled Visit on Apr/14/2021

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

5.c Sample ID

Date	Location	User	Value	Reason
Apr-14-2021 09:49:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BSJ448	Initial Entry

5.d

Date	Location	User	Value	Reason
Apr-14-2021 09:50:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BSJ449	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Apr-14-2021 09:50:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BSJ449	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-29-2021 16:56:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Jan/25/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-29-2021 16:56:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-29-2021 16:56:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History
Unscheduled

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

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Apr-06-2021 12:04:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	Data Entry: Apr/2/2021	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Apr-12-2021 14:48:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Closed	Close Auto Query
Apr-07-2021 03:27:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Apr-06-2021 12:05:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	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

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -
Unscheduled eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

Site No: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294 **Subject Initials:** ---

Generated By: (b) (4) **Generated Time (GMT):** 10-Nov-2021 20:44

				this date.
Apr-06-2021 12:05:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Date	Location	User	Value	Reason
Dec-28-2020 13:07:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

Date	Location	User	Value	Reason
Apr-16-2021 08:39:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Dec-28-2020 13:07:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-28-2020 13:07:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-28-2020 13:07:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: bilateral shoulder pain	Initial Entry

4. Start Date Time:

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Dec-28-2020 13:07:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Dec/22/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-28-2020 13:07:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO End Date Time: Dec/24/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-28-2020 13:07:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Dec-28-2020 13:07:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Dec-28-2020 13:07:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Dec-28-2020 13:07:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to : OTHER <i>If Other, specify:</i>	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

lifting heavy object

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-28-2020 13:07:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-28-2020 13:07:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-28-2020 13:07:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Dec-28-2020 13:07:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(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-28-2020 13:07:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Apr-16-2021 08:39:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Apr-16-2021 08:39:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Apr-16-2021 08:39:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: body aches	Initial Entry

4. Start Date Time:

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Apr-16-2021 08:39:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Apr/6/2021 18:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Apr-16-2021 08:39:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO End Date Time: Apr/7/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Apr-16-2021 08:39:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Apr-16-2021 08:39:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Apr-16-2021 08:39:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Apr-16-2021 08:39:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Apr-16-2021 08:39:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Apr-16-2021 08:39:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Apr-16-2021 08:39:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Apr-16-2021 08:39:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

& Canada)				
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Apr-16-2021 08:39:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Apr-12-2021 14:48:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Apr/2/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Apr-12-2021 14:48:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FO R ADDITIONAL VACCIN ATION	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Apr-06-2021 12:05:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	Data Entry: Apr/6/2021	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER
VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Apr-06-2021 12:05:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtai ned Apr/6/2021	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Apr-06-2021 12:06:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Apr/6/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Apr-06-2021 12:06:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Apr-06-2021 12:06:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 28-Mar-2021 02:27

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Apr-06-2021 12:06:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Apr-06-2021 12:06:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Apr-06-2021 12:06:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Apr/6/2021	Initial Entry

4. Laboratory Name and Address (Derived)

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 28-Mar-2021 02:27

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Apr-06-2021 12:06:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Apr-06-2021 12:06:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Apr-06-2021 12:06:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX 113 Result:: NEGATIVE Not Done::	Initial Entry

6.a Sponsor ID:

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 28-Mar-2021 02:27

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Apr-06-2021 12:06:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Apr-06-2021 12:06:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX 113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Apr-06-2021 12:06:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Apr-06-2021 12:06:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Apr-06-2021 12:06:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Apr-06-2021 12:19:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Apr-06-2021 12:06:45	ACV0PF EINFP60	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00			Yes, however no barcodes are entered. Please review and correct as appropriate.
Apr-06-2021 12:06:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Apr/6/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Apr-06-2021 12:19:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BR9DN3	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Apr-06-2021 12:19:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BR9DN3	Initial Entry

5.b

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
Apr-06-2021 12:19:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BSJ43Z	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Apr-06-2021 12:19:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BSJ43Z	Initial Entry

5.c

Date	Location	User	Value	Reason
Apr-06-2021 12:19:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BRTSP1	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

5.c Sample ID

Date	Location	User	Value	Reason
Apr-06-2021 12:19:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [Redacted]	Data Entry: BRTSP1	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Apr-06-2021 12:07:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Apr-06-2021 12:07:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Apr-06-2021 12:20:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Apr-06-2021 12:07:15	ACV0PF EINFP60	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00			Yes, however no barcodes are entered. Please review and correct as appropriate.
Apr-06-2021 12:07:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Apr/6/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Apr-06-2021 12:20:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BR9DT8	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Apr-06-2021 12:20:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BR9DT8	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Apr-06-2021 12:07:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Apr-06-2021 12:07:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Apr-06-2021 12:07:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Apr-06-2021 12:07:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Apr/6/2021 09:22	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
Apr-06-2021 12:07:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Apr-06-2021 12:07:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Apr-06-2021 12:07:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

8. Actual Dose:

Date	Location	User	Value	Reason
Apr-06-2021 12:07:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Apr-06-2021 12:07:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Apr-06-2021 12:07:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
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090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Apr-06-2021 12:07:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6) [REDACTED]	Data Entry: YES	Initial Entry
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090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
May-07-2021 12:22:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Apr/28/2021	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 28-Mar-2021 02:27

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
May-07-2021 12:22:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
May-07-2021 12:22:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
May-07-2021 12:22:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Apr/28/2021	Initial Entry

4. Laboratory Name and Address (Derived)

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 28-Mar-2021 02:27

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
May-07-2021 12:22:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
May-07-2021 12:22:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
May-07-2021 12:22:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX 113 Result:: NEGATIVE Not Done::	Initial Entry

6.a Sponsor ID:

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 28-Mar-2021 02:27

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

Date	Location	User	Value	Reason
May-07-2021 12:22:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
May-07-2021 12:22:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_P X113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
May-07-2021 12:22:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
May-07-2021 12:23:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
May-07-2021 12:23:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
May-07-2021 12:26:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto query (autoquery)	Query 1: Deleted	Close Auto Query
May-07-2021 12:23:10	ACV0PF EINFP60	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00			Yes, however no barcodes are entered. Please review and correct as appropriate.
May-07-2021 12:23:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Apr/28/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
May-07-2021 12:26:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Sample ID: BR9DRH	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
May-07-2021 12:26:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: BR9DRH	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
May-07-2021 12:24:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
May-07-2021 12:24:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
May-07-2021 12:24:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
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090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

May-07-2021 12:24:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Apr/28/2021 09:35	Initial Entry
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5. Anatomical Location:

Date	Location	User	Value	Reason
May-07-2021 12:24:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
May-07-2021 12:24:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
May-07-2021 12:24:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

8. Actual Dose:

Date	Location	User	Value	Reason
May-07-2021 12:24:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
May-07-2021 12:24:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
May-07-2021 12:24:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
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090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

May-07-2021 12:24:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Jun-01-2021 13:44:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Madison Ellis (b) (4)	Data Entry: Jun/1/2021	Initial Entry

Header Text: c4591001

Visit: V103_MONTH1

Form: CONTACT OUTCOME - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Contact Type:

Date	Location	User	Value	Reason
Jun-01-2021 13:45:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Jun-01-2021 13:45:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Madison Ellis (b) (4)	Data Entry: YES Date of Contact: Jun/1/2021	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit:
FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit
Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jun-01-2021 13:45:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Madison Ellis (b) (4)	Data Entry: Jun/1/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jun-01-2021 13:45:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: OPEN LABEL TREATMENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jun-01-2021 13:45:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Madison Ellis (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Jan-29-2021 16:56:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Dec-07-2020 12:38:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Dec-07-2020 12:34:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Jan-29-2021 16:56:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Jan/25/2021	Initial Entry
Jan-22-2021 03:00:30	ACV0PF EINFP60	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

(UTC-07:00) Mountain Time (US & Canada)	00	(b) (4), (b) (6)		
Jan-21-2021 17:14:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	deemed not required
Jan-07-2021 22:10:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Reissued:Opened	RQ1: Response states 'illness visit not required'. Please confirm if Illness eduary entry on 23Dec2020 was deemed erroneous and that subject had no Covid Illness symptoms.
Jan-07-2021 11:28:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Query 1: Answered	illness visit not required
Dec-29-2020 11:22:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	Balaji Prabu R (b) (4)	Query 1: Opened	Illness eduary: As per Illness eduary records, subject reported "Yes" for the

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091294

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 10-Nov-2021 20:44

				question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 23Dec2020. But there is no COVID Illness visit reported. Please clarify.
Dec-07-2020 12:38:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Dec/7/2020	Initial Entry
Dec-07-2020 12:34:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	auto calc (autocalc)	Data Entry: Dec/7/2020	Initial Entry

090177e19891a03d\Final\Final On: 11-Nov-2021 01:20 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1009

Subject No: 10091294

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit
Trail History

Form Status: Data Complete, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family
Clinic South

Subject Initials: ---

Generated Time (GMT): 10-Nov-2021 20:44

[Back to Form](#)

1. Casebook Signature

Date	Location	User	Value	Reason
Mar-10-2021 16:13:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PF EINFP60 00	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry