

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT\_SELECTION

**Form Version:** 30-Jul-2020 21:29

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Cohort Selection**

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

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

<b>Header Text:</b> c4591001	<b>Form:</b> MAIN INFORMED CONSENT
<b>Visit:</b> COHORT_SELECTION	<b>Form Status:</b> Data Complete, Locked, Frozen, Verified
<b>Form Version:</b> 22-Apr-2020 21:02	<b>Site Name:</b> (1136) Clinical Research Center of Nevada
<b>Site No:</b> 1136	<b>Subject Initials:</b> ---
<b>Subject No:</b> 11361029	<b>Generated Time (GMT):</b> 19-Apr-2021 21:04
<b>Generated By:</b> (b) (4)	

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/20/2020
----	--------------	--

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** DEMOGRAPHY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[11361029]
2.	Birth Date:	(b) (6)/1978
3.	Sex:	FEMALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Aug/20/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

**Form Comments**

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation /Death	Aug/20/2020
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: 1136

Subject No: 11361029

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1136) Clinical Research Center of Nevada

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[nasal polyps]
	Start Date:	UNK/UNK/2014
	Ongoing:	NO End Date: UNK/UNK/2014
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[asthma]
	Start Date:	UNK/UNK/2007
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[pneumonia]
	Start Date:	UNK/UNK/2007
	Ongoing:	NO End Date: UNK/UNK/2007
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[uterine fibroids]
	Start Date:	UNK/UNK/2013
	Ongoing:	NO End Date: UNK/UNK/2013

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[epilepsy]
	Start Date:	UNK/UNK/2002
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[migraine headaches]
	Start Date:	UNK/UNK/1991
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[generalized anxiety]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[seasonal allergies]
	Start Date:	UNK/UNK/1988
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[laparoscopic hysterectomy]
	Start Date:	UNK/UNK/2013
	Ongoing:	NO End Date: UNK/UNK/2013

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[sinus surgery]
	Start Date:	UNK/UNK/2014
	Ongoing:	NO End Date: UNK/UNK/2014

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - BASELINE

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Aug/20/2020
2.	Weight:	[145.0]
3.	Unit:	LB
4.	Height:	[66.0]
5.	Unit:	in
6.	Body Mass Index:	[23.4]

**Vital Signs Details**

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

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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

**Lab Urinalysis**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Lab Sub-Panel:	Not Applicable _____	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Laboratory Name and Address (Derived)	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

6.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** RANDOMIZATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Aug/20/2020
2.	Randomization Number:	[59449]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/20/2020
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	[BP57RX]
5.b	Sample ID	[BP57RY]
5.c	Sample ID	[BP57RZ]
5.d	Sample ID	[BPRSGM]
5.e	Sample ID	[BPRSGN]
5.f	Sample ID	[BPRSGP]

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/20/2020
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	[BP57P6]
-----	-----------	----------

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/20/2020 14:02
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

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

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



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Date of Visit**

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

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[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?	YES Ongoing? NO Stop Date: Aug/28/2020
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

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 21-Aug-2020 02:52

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

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

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:54

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/11/2020
----	-------	-------------

**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[98.6]
	Unit:	F
	Temperature Location:	ORAL CAVITY

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 30-Jul-2020 21:27**Site No:** 1136**Subject No:** 11361029**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1136) Clinical Research Center of Nevada**Subject Initials:** ---**Generated Time (GMT):** 19-Apr-2021 21:04

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

**Lab Urinalysis**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Lab Sub-Panel:	Not Applicable _____	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Laboratory Name and Address (Derived)	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

6.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/11/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP57X5]
-----	-----------	----------

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/11/2020 15:44
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Date of Visit**

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



Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[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?	Not Applicable	<a href="#">Comments</a>
2.a	Symptom:	FEVER	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
2.b	Symptom:	FATIGUE	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
2.c	Symptom:	HEADACHE	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
2.d	Symptom:	CHILLS	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
2.e	Symptom:	VOMITING	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
2.f	Symptom:	DIARRHEA	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

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

**Form Version:** 21-Aug-2020 02:52

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
3.	Injection Site Location:		
4.	Injection Site Body Side:	Not Applicable	<a href="#">Comments</a>
5.a	Injection Site Reaction:	REDNESS	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
5.b	Injection Site Reaction:	SWELLING	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE	
	Were injection site reactions present on the last day the Subject Diary was completed?	Not Applicable	<a href="#">Comments</a>

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/12/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BM91MZ]
5.b	Sample ID	[BM91N0]
5.c	Sample ID	[BM91N1]
5.d	Sample ID	[BPRSL0]
5.e	Sample ID	[BPRSL1]

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/10/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP586T]
5.b	Sample ID	[BP586V]
5.c	Sample ID	[BP586W]
5.d	Sample ID	[BPRSWT]

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

**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	[ ]
----	-----------	-----

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET  
on Nov/09/2020

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Nov/9/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19  
on Nov/09/2020

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Signs and Symptoms**

1.	Date of Assessment:	Nov/9/2020
2.	Date of First Symptom Started:	Nov/4/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Nov/19/2020

**Symptoms**

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

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020      **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

**Symptoms - Other**

5.a	Symptoms - Other Text:	[HEADACHE]
5.b	Symptoms - Other Text:	[SINUS CONGESTION]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

#	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	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** MICROBIOLOGY SPECIMEN  
on Nov/09/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

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

**Microbiology Specimen**

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

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Nov/09/2020

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[SUBJECT CAME INTO THE SITE FOR SWAB COLLECTION]

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
on Nov/09/2020

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Nov/9/2020
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	[BRFWTR]
-----	-----------	----------

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION  
on Nov/09/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1136**Site Name:** (1136) Clinical Research Center of Nevada**Subject No:** 11361029**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 19-Apr-2021 21:04[eCRF Audit Trail History](#)**Health Care Utilization**

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

**Health Care Utilization Other**

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

**Health Care Utilization**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** RESPIRATORY TREATMENT

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** RESPIRATORY TREATMENT  
on Nov/09/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

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

**Respiratory Treatment**

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

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS  
on Nov/09/2020

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[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:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

#	Category of Clinical Event	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** ILLNESS DETAILS - SEVERE  
on Nov/09/2020

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

**Illness Details**

1.	Category of Clinical Event:	Not Applicable _____	<a href="#">Comments</a>
2.	Subcategory of Clinical Event:	Not Applicable _____	<a href="#">Comments</a>
3.	Was a diagnosis obtained?	Not Applicable _____	<a href="#">Comments</a>
4.	Toxicity Grade:	Not Applicable _____	<a href="#">Comments</a>

Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 30-Jul-2020 21:27

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Done	Not Done	Not Done	Not Done	<b>Sponsor-Defined Identifier</b>	<b>Test:</b>	<b>Result:</b>	<a href="#">Repeating Pages</a>
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Nov/09/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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

**Lab Chemistry Details**

1.	Lab Panel:	Not Done _____	<a href="#">Comments</a>
2.	Laboratory Name and Address	Not Done _____ [ ]	<a href="#">Comments</a>
3.	Collection Date:	Not Done _____ //	<a href="#">Comments</a>
4.	Specimen Type:	Not Done _____	<a href="#">Comments</a>

**Lab Result**

5.a	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	C Reactive Protein_PX329	
	Result:	Not Done _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Done _____	<a href="#">Comments</a>
	LNMT	Not Done _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Nov/09/2020

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

5.b	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Done _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Done _____	<a href="#">Comments</a>
	LNMT	Not Done _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

5.c	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Done _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Done _____	<a href="#">Comments</a>
	LNMT	Not Done _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Nov/09/2020

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

5.d	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Done _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Done _____	<a href="#">Comments</a>
	LNMT	Not Done _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

5.e	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	Bilirubin_PX21	
	Result:	Not Done _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Done _____	<a href="#">Comments</a>
	LNMT	Not Done _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Nov/09/2020

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

5.f	Sponsor ID:	Not Done _____	<a href="#">Comments</a>
		[ ]	
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Done _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Done _____	<a href="#">Comments</a>	
LNMT	Not Done _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

5.g	Sponsor ID:	Not Done _____	<a href="#">Comments</a>
		[ ]	
	Test:	Creatinine_PX48	
	Result:	Not Done _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Done _____	<a href="#">Comments</a>	
LNMT	Not Done _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Done	Not Done	Not Done	Not Done	<b>Sponsor-Defined Identifier</b>	<b>Test:</b>	<b>Result :</b>	<a href="#">Repeating Pages</a>
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology on Nov/09/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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

**Laboratory Data Hematology**

1.	Lab Panel:	Not Done _____	<a href="#">Comments</a>
2.	Laboratory Name and Address	Not Done _____ [ ]	<a href="#">Comments</a>
3.	Collection Date:	Not Done _____ //	<a href="#">Comments</a>
4.	Specimen Type:	Not Done _____	<a href="#">Comments</a>

**Lab Result**

5.a	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	Hemoglobin_PX1	
	Result:	Not Done _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Done _____	<a href="#">Comments</a>
	LNMT	Not Done _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/09/2020

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

5.b	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	Hematocrit_PX2	
	Result:	Not Done _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Done _____	<a href="#">Comments</a>
	LNMT	Not Done _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

5.c	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	Erythrocytes_PX3	
	Result:	Not Done _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Done _____	<a href="#">Comments</a>
	LNMT	Not Done _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
on Nov/09/2020

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

5.d	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	Platelets_PX5	
	Result:	Not Done _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Done _____	<a href="#">Comments</a>
	LNMT	Not Done _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

5.e	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	Leukocytes_PX7	
	Result:	Not Done _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Done _____	<a href="#">Comments</a>
	LNMT	Not Done _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/09/2020

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

5.f	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	Neutrophils_PX608	
	Result:	Not Done _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Done _____	<a href="#">Comments</a>
	LNMT	Not Done _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

5.g	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	Eosinophils_PX609	
	Result:	Not Done _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Done _____	<a href="#">Comments</a>
	LNMT	Not Done _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology on Nov/09/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

5.h	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	Monocytes_PX612	
	Result:	Not Done _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Done _____	<a href="#">Comments</a>
	LNMT	Not Done _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

5.i	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	Basophils_PX610	
	Result:	Not Done _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Done _____	<a href="#">Comments</a>
	LNMT	Not Done _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
on Nov/09/2020

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

5.j	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	Lymphocytes_PX611	
	Result:	Not Done _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Done _____	<a href="#">Comments</a>
	LNMT	Not Done _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** VITAL SIGNS - COVID

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

#	Date:	Vital Signs Details			Form Instance
1.	Nov/9/2020	<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>
		1	112	84	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** VITAL SIGNS - COVID  
on Nov/09/2020

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

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

**Vital Signs**

1.	Date:	Nov/9/2020
----	-------	------------

**Vital Signs Details**

2.a	Record Identifier:	1
	Systolic:	[112]
	Diastolic:	[84]
	Respiratory Rate in respirations/minute:	[18]
	Heart Rate in beats/minute:	[72]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

#	Date:	Vital Signs Details		Form Instance
1.	Nov/9/2020	<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>
		1	97.0	

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
on Nov/09/2020

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

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

**Vital Signs**

1.	Date:	Nov/9/2020
----	-------	------------

**Vital Signs Details**

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[97.0]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** OXYGENATION PARAMETERS

**Form Version:** 06-Jul-2020 21:52

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Not Done	Not Done	Not Done	<a href="#">Repeating Pages</a>

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS  
on Nov/09/2020

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Oxygenation Parameters**

1.	Date Time of Assessment:	Not Done _____ //	<a href="#">Comments</a>
2.	Arterial Blood Gases PaO2 (mmHg):	Not Done _____ [ ]	<a href="#">Comments</a>
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Done _____ [ ]	<a href="#">Comments</a>



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	<a href="#">Repeating Pages</a>

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS  
on Nov/09/2020

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Concomitant Medications**

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

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** IMAGING

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** IMAGING  
on Nov/09/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Imaging**

1.	Date of Assessment:	Not Done _____ //	<a href="#">Comments</a>
2.	Location of Assessment:	Not Done _____	<a href="#">Comments</a>
3.	Type of Imaging Exam:	Not Done _____	<a href="#">Comments</a>
4.	Assessment:	Not Done _____	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA - New  
Unscheduled Visit

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Not Started

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA - New  
Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

**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 Visit

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

**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:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

**Unplanned Assessments**

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



**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** DISPOSITION - TREATMENT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Disposition - Treatment**

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

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

**Disposition - Follow-Up**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New  
Unscheduled Visit

**Form:** DATE OF VISIT - REPEAT SWAB

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New  
Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	worsening of intermittent seizures	Dec/1/2020 00:00	NO End Date Time: Jan/25/2021 00:00	<a href="#">Repeating Pages</a>

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[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)	[worsening of intermittent seizures]
4.	Start Date Time:	Dec/1/2020 00:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/25/2021 00:00
6.	Toxicity Grade:	1
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: [Med Hx of epilepsy]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						<a href="#">Repeating Pages</a>



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[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	[ ]

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

**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:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[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:	//

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[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?	

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

**Radiation Treatment**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

#	Transfusion Type	Date of Transfusion	Form Instance
1.			<a href="#">Repeating Pages</a>



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VITAL SIGNS - TEMP

**Form Version:** 20-Feb-2021 02:16

**Form Status:** Not Started

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

**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:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

**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:	

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Not Started

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

**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?	

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (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:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

**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:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

**Form Version:** 14-Jan-2021 02:29

**Form Status:** Not Started

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

**Informed Consent - Asymptomatic Surveillance**

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

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/14/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** FURTHER VACCINATION CONFIRMATION

**Form Version:** 10-Dec-2020 02:25

**Form Status:** Data Complete, Frozen

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** TREATMENT UNBLINDED

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Jan/14/2021
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:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Form Comments](#)

[eCRF Audit Trail History](#)

**Withdrawal Of Consent**

1.	Withdrawal of Consent Date :	Not Applicable _____ //	<a href="#">Comments</a>
----	------------------------------	-------------------------------	--------------------------

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** DEATH DETAILS CODED

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Form Comments](#)

[eCRF Audit Trail History](#)

**Death Details**

1.	Date of Collection / Notification of Death:	Not Applicable _____ //	<a href="#">Comments</a>
----	---	-------------------------------	--------------------------

**Cause of Death**

2.	Cause of Death Status:	Not Applicable _____
	Cause of Death:	Not Applicable _____ [ ]



**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Subject Status**

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

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[eCRF Audit Trail History](#)

**Casebook Signature Form**

1.	Casebook Signature	<a href="#">Click Here to Enable</a>
----	--------------------	--------------------------------------

**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:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Audit Trail](#)

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

- CRF\_Sign
- CRF\_Sign\_1

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

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-20-2020 14:40:45 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-20-2020 14:47:09 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [Redacted]	not of child bearing potential <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
1	Aug-20-2020 14:47:09 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	not of child bearing potential <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
2	Aug-20-2020 14:47:09 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [Redacted]	not of child bearing potential <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
3	Aug-20-2020 14:47:09 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [Redacted]	not of child bearing potential <hr/> Not Applicable



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
4	Aug-20-2020 14:47:09 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [Redacted]	not of child bearing potential <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5	Aug-20-2020 14:47:09 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [Redacted]	not of child bearing potential <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
6.a	Aug-20-2020 14:47:09 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [Redacted]	not of child bearing potential <hr/> Not Applicable

**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 30-Jul-2020 21:27  
**Site No:** 1136  
**Subject No:** 11361029  
**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site Name:** (1136) Clinical Research Center of Nevada  
**Subject Initials:** ---  
**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
6.a	Aug-20-2020 14:47:09 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	not of child bearing potential
			Not Applicable

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
6.a	Aug-20-2020 14:47:09 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	not of child bearing potential
			Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-18-2020 12:39:04 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	NOCBP Not Applicable
Form	Sep-18-2020 12:38:56 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	NOCBP

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
1	Sep-18-2020 12:39:04 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	NOCBP Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
2	Sep-18-2020 12:39:04 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	NOCBP Not Applicable



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
3	Sep-18-2020 12:39:04 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	NOCBP
			Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
4	Sep-18-2020 12:39:04 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	NOCBP Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5	Sep-18-2020 12:39:04 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	NOCBP Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
6.a	Sep-18-2020 12:39:04 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	NOCBP Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
6.a	Sep-18-2020 12:39:04 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	NOCBP
			Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
6.a	Sep-18-2020 12:39:04 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	NOCBP Not Applicable

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

**Form Version:** 21-Aug-2020 02:52

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
1	Nov-10-2020 13:46:57 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

**Form Version:** 21-Aug-2020 02:52

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
2.a	Nov-10-2020 13:49:20 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

**Form Version:** 21-Aug-2020 02:52

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
2.b	Nov-10-2020 13:49:30 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

**Form Version:** 21-Aug-2020 02:52

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
2.c	Nov-10-2020 13:51:26 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

**Form Version:** 21-Aug-2020 02:52

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
2.d	Nov-10-2020 13:51:35 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

**Form Version:** 21-Aug-2020 02:52

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
2.e	Nov-10-2020 13:51:44 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

**Form Version:** 21-Aug-2020 02:52

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
2 f	Nov-10-2020 13:51:53 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

**Form Version:** 21-Aug-2020 02:52

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
2.g	Nov-10-2020 13:52:04 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

**Form Version:** 21-Aug-2020 02:52

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
2 h	Nov-10-2020 13:52:13 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

**Form Version:** 21-Aug-2020 02:52

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
4	Nov-10-2020 13:52:22 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

**Form Version:** 21-Aug-2020 02:52

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.a	Nov-10-2020 13:52:45 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

**Form Version:** 21-Aug-2020 02:52

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.b	Nov-10-2020 13:52:55 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - Comments

**Form Version:** 21-Aug-2020 02:52

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.c	Nov-10-2020 13:53:05 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Nov/09/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-10-2020 09:07:35 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
1	Nov-10-2020 09:07:35 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Nov/09/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
2	Nov-10-2020 09:07:35 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Nov/09/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
3	Nov-10-2020 09:07:35 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Nov/09/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
4	Nov-10-2020 09:07:35 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Nov/09/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5	Nov-10-2020 09:07:35 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Nov/09/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
6	Nov-10-2020 09:07:35 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020      **Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
7	Nov-10-2020 09:07:35 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Nov/09/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
8	Nov-10-2020 09:07:35 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
9	Nov-10-2020 09:07:35 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** RESPIRATORY TREATMENT - Comments  
on Nov/09/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-12-2020 15:57:21 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Nov/09/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
1	Nov-12-2020 15:57:21 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Nov/09/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
2	Nov-12-2020 15:57:21 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Nov/09/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
3	Nov-12-2020 15:57:21 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done
3	Nov-12-2020 08:58:50 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
3	Nov-10-2020 09:10:26 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Nov/09/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
4	Nov-12-2020 15:57:21 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Nov/09/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5	Nov-12-2020 15:57:21 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done
5	Nov-12-2020 08:59:08 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
5	Nov-10-2020 09:10:53 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Nov/09/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
6	Nov-12-2020 15:57:21 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done
6	Nov-10-2020 09:12:58 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
6	Nov-10-2020 09:11:09 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** ILLNESS DETAILS - SEVERE - Comments  
on Nov/09/2020

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-12-2020 08:58:20 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** ILLNESS DETAILS - SEVERE - Comments  
on Nov/09/2020

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
1	Nov-12-2020 08:58:20 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments  
on Nov/09/2020

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
2	Nov-12-2020 08:58:20 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
2	Nov-10-2020 09:13:52 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments  
on Nov/09/2020

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
3	Nov-12-2020 08:58:20 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments  
on Nov/09/2020

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
4	Nov-12-2020 08:58:20 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
4	Nov-10-2020 09:14:14 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
1	Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
2	Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
3	Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
4	Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.a	Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.a	Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.a	Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.a	Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.b	Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.b	Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.b	Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.b	Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.c	Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.c	Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.c	Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.c	Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.d	Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.d	Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.d	Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.d	Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.e	Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.e	Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.e	Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.e	Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5 f	Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5 f	Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5 f	Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5 f	Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.g	Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.g	Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.g	Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.g	Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
1	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
2	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
3	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
4	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.a	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.a	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.a	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.a	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.b	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.b	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.b	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.b	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.c	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.c	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.c	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.c	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.d	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.d	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.d	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.d	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.e	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.e	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.e	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.e	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5 f	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5 f	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5 f	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5 f	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.g	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.g	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.g	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.g	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5 h	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5 h	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5 h	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5 h	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.i	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.i	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.i	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.i	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.j	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.j	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.j	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5.j	Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments  
on Nov/09/2020

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-10-2020 09:22:13 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** OXYGENATION PARAMETERS - Comments

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
1	Nov-10-2020 09:22:13 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** OXYGENATION PARAMETERS - Comments

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
2	Nov-10-2020 09:22:13 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020 **Form:** OXYGENATION PARAMETERS - Comments

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
3	Nov-10-2020 09:22:13 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-10-2020 09:22:29 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
1	Nov-10-2020 09:22:29 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
2	Nov-10-2020 09:22:29 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
3	Nov-10-2020 09:22:29 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
4	Nov-10-2020 09:22:29 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
5	Nov-10-2020 09:22:29 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
6	Nov-10-2020 09:22:29 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** IMAGING - Comments  
on Nov/09/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-10-2020 09:22:45 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** IMAGING - Comments  
on Nov/09/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
1	Nov-10-2020 09:22:45 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** IMAGING - Comments  
on Nov/09/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
2	Nov-10-2020 09:22:45 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** IMAGING - Comments  
on Nov/09/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
3	Nov-10-2020 09:22:45 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** IMAGING - Comments  
on Nov/09/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
4	Nov-10-2020 09:22:45 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** WITHDRAWAL OF CONSENT - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-21-2021 12:13:31 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** Disposition

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** WITHDRAWAL OF CONSENT - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
1	Jan-21-2021 12:13:31 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** DEATH DETAILS CODED - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-21-2021 12:13:50 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Disposition

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** DEATH DETAILS CODED - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Item	Date	User	Comment
1	Jan-21-2021 12:13:50 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[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	Feb-09-2021 11:42:29 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

**Affidavit:**

N/A

Michael Levin	Approved	Jan-22-2021 12:16:09 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
---------------	----------	---	------	--------

**Affidavit:**

By my dated signature below, I, MichaelLevin, 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	Jan-19-2021 10:20:19 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
---------	-----	---	--	-----------------------------------

**Affidavit:**

N/A

Michael Levin	Approved	Nov-16-2020 13:13:08 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
---------------	----------	---	------	--------

**Affidavit:**

By my dated signature below, I, MichaelLevin, 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.

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** COHORT\_SELECTION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

**1. Select appropriate response - Protocol version**

Date	Location	User	Value	Reason
Aug-20-2020 14:39:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-20-2020 14:39:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

***1. Consent Was:***

Date	Location	User	Value	Reason
Aug-20-2020 14:40:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Aug/20/2020	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1136

Subject No: 11361029

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1136) Clinical Research Center of Nevada

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

**1. Subject ID**

Date	Location	User	Value	Reason
Aug-20-2020 14:39:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11361029	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-20-2020 14:39:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1978	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-20-2020 14:40:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Aug-20-2020 14:40:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HISPANIC OR LATINO(A) OR O F SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-20-2020 14:40:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

*I. Date of Visit*

Date	Location	User	Value	Reason
Aug-20-2020 14:40:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/20/2020	Initial Entry



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Aug-20-2020 14:41:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/20/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-20-2020 14:41:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Aug-20-2020 14:41:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

*1.a*

Date	Location	User	Value	Reason
Aug-20-2020 14:41:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History Term:</b> nasal polyps <b>Start Date:</b> UNK/UNK/2014 <b>Ongoing:</b> NO End Date:  UNK/UNK/ 2014	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Aug-20-2020 14:41:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-20-2020 14:41:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> nasal polyps	Initial Entry

*1.a Start Date:*

Date	Location	User	Value	Reason
Aug-20-2020 14:41:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2014	Initial Entry

*1.a Ongoing:*

Date	Location	User	Value	Reason
------	----------	------	-------	--------

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

Aug-20-2020 14:41:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2014	Initial Entry
---	-----------------	---------------------	---	---------------

*I.b*

Date	Location	User	Value	Reason
Aug-20-2020 14:41:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 2 <b>Medical History Term:</b> asthma <b>Start Date:</b> UNK/UNK/2007 <b>Ongoing:</b> YES	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1136

Subject No: 11361029

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1136) Clinical Research Center of Nevada

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

**1.b Line/MH Number:**

Date	Location	User	Value	Reason
Aug-20-2020 14:41:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-20-2020 14:41:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> asthma	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Aug-20-2020 14:41:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2007	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
Aug-20-2020 14:41:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.c**

Date	Location	User	Value	Reason
Aug-20-2020 14:42:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 3 <b>Medical History Term:</b> pneumonia <b>Start Date:</b> UNK/UNK/2007 <b>Ongoing:</b> NO End Date: UNK/UNK/2007	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1136

Subject No: 11361029

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1136) Clinical Research Center of Nevada

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

**I.c Line/MH Number:**

Date	Location	User	Value	Reason
Aug-20-2020 14:42:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-20-2020 14:42:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> pneumonia	Initial Entry

**I.c Start Date:**

Date	Location	User	Value	Reason
Aug-20-2020 14:42:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2007	Initial Entry

**I.c Ongoing:**

Date	Location	User	Value	Reason
Aug-20-2020 14:42:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2007	Initial Entry

**I.d**

Date	Location	User	Value	Reason
Aug-20-2020 14:42:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 4 <b>Medical History:</b> uterine fibroids <b>Term:</b> <b>Start Date:</b> UNK/UNK/2013	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1136

Subject No: 11361029

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1136) Clinical Research Center of Nevada

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

			Ongoing:	NO	
				End Date:	
				UNK/UNK/2013	

**I.d Line/MH Number:**

Date	Location	User	Value	Reason
Aug-20-2020 14:42:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-20-2020 14:42:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> uterine fibroids	Initial Entry

**I.d Start Date:**

Date	Location	User	Value	Reason
Aug-20-2020 14:42:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/2013	Initial Entry

**I.d Ongoing:**

Date	Location	User	Value	Reason
Aug-20-2020 14:42:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date:  UNK/UNK/2013	Initial Entry

**I.e**

Date	Location	User	Value	Reason
Aug-20-2020 14:42:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Number: 5 Medical History Term: epilepsy	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1136

Subject No: 11361029

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1136) Clinical Research Center of Nevada

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

			<b>Start Date:</b>	UNK/UNK/2002	
			<b>Ongoing:</b>	YES	

*I.e Line/MH Number:*

Date	Location	User	Value	Reason
Aug-20-2020 14:42:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-20-2020 14:42:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> epilepsy	Initial Entry

*I.e Start Date:*

Date	Location	User	Value	Reason
Aug-20-2020 14:42:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2002	Initial Entry

*I.e Ongoing:*

Date	Location	User	Value	Reason
Aug-20-2020 14:42:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

*I.f*

Date	Location	User	Value	Reason
Aug-20-2020 14:43:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 6 <b>Medical History Term:</b> migraine headaches <b>Start Date:</b> UNK/UNK/1991	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1136

Subject No: 11361029

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1136) Clinical Research Center of Nevada

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

			Ongoing:	YES
--	--	--	----------	-----

*1.f Line/MH Number:*

Date	Location	User	Value	Reason
Aug-20-2020 14:43:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 6	Initial Entry

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

Date	Location	User	Value	Reason
Aug-20-2020 14:43:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> migraine headaches	Initial Entry

*1.f Start Date:*

Date	Location	User	Value	Reason
Aug-20-2020 14:43:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> UNK/UNK/1991	Initial Entry

*1.f Ongoing:*

Date	Location	User	Value	Reason
Aug-20-2020 14:43:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

*1.g*

Date	Location	User	Value	Reason
Aug-20-2020 14:43:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Number 7 : Medical History T generalized an erm: anxiety Start Date: UNK/UNK/20 15 Ongoing: YES	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1136

Subject No: 11361029

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1136) Clinical Research Center of Nevada

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

***1.g Line/MH Number:***

Date	Location	User	Value	Reason
Aug-20-2020 14:43:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

***1.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Aug-20-2020 14:43:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> generalized anxiety	Initial Entry

***1.g Start Date:***

Date	Location	User	Value	Reason
Aug-20-2020 14:43:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2015	Initial Entry

***1.g Ongoing:***

Date	Location	User	Value	Reason
Aug-20-2020 14:43:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.h***

Date	Location	User	Value	Reason
Aug-20-2020 14:43:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 8 <b>Medical History Term:</b> seasonal allergies <b>Start Date:</b> UNK/UNK/1988 <b>Ongoing:</b> YES	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1136

Subject No: 11361029

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1136) Clinical Research Center of Nevada

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

***1.h Line/MH Number:***

Date	Location	User	Value	Reason
Aug-20-2020 14:43:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 8	Initial Entry

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

Date	Location	User	Value	Reason
Aug-20-2020 14:43:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> seasonal allergies	Initial Entry

***1.h Start Date:***

Date	Location	User	Value	Reason
Aug-20-2020 14:43:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1988	Initial Entry

***1.h Ongoing:***

Date	Location	User	Value	Reason
Aug-20-2020 14:43:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.i***

Date	Location	User	Value	Reason
Aug-20-2020 14:45:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Line/MH Nu</b> 9 <b>mber:</b> <b>Medical Histo</b> laparoscopic hyst <b>ry Term:</b> erectomy <b>Start Date:</b> UNK/UNK/2013 <b>Ongoing:</b> NO End Date:  UNK/UNK/20 13	Transcription Error

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

Aug-20-2020 14:44:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 9 <b>Medical History Term:</b> laproscopic hysterectomy <b>Start Date:</b> UNK/UNK/2013 <b>Ongoing:</b> NO End Date:  UNK/UNK/2013	Initial Entry
---	-----------------	-------------------------	---	---------------

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1136

Subject No: 11361029

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1136) Clinical Research Center of Nevada

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

***1.i Line/MH Number:***

Date	Location	User	Value	Reason
Aug-20-2020 14:44:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 9	Initial Entry

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

Date	Location	User	Value	Reason
Aug-20-2020 14:45:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> laparoscopic hysterectomy	Transcription Error
Aug-20-2020 14:44:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> laparoscopic hysterectomy	Initial Entry

***1.i Start Date:***

Date	Location	User	Value	Reason
Aug-20-2020 14:44:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2013	Initial Entry

***1.i Ongoing:***

Date	Location	User	Value	Reason
Aug-20-2020 14:44:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2013	Initial Entry

***1.j***

Date	Location	User	Value	Reason
Aug-20-2020 14:45:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 10 <b>Medical History Term:</b> sinus surgery <b>Start Date:</b> UNK/UNK/2014	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1136

Subject No: 11361029

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1136) Clinical Research Center of Nevada

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

			<b>Ongoing:</b>	NO	
				End Date:	
				UNK/UNK/	
				2014	

**1.j Line/MH Number:**

Date	Location	User	Value	Reason
Aug-20-2020 14:45:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10	Initial Entry

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

Date	Location	User	Value	Reason
Aug-20-2020 14:45:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> sinus surgery	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

***1.j Start Date:***

Date	Location	User	Value	Reason
Aug-20-2020 14:45:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2014	Initial Entry

***1.j Ongoing:***

Date	Location	User	Value	Reason
Aug-20-2020 14:45:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2014	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:28

Site No: 1136

Subject No: 11361029

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1136) Clinical Research Center of Nevada

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Aug-20-2020 14:46:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/20/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-20-2020 14:46:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 145.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-20-2020 14:46:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Aug-20-2020 14:46:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 66.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Aug-20-2020 14:46:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> in	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Aug-20-2020 14:46:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 23.4	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:28

Site No: 1136

Subject No: 11361029

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1136) Clinical Research Center of Nevada

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

7.a

Date	Location	User	Value	Reason
Aug-20-2020 14:46:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 98.3 <b>Temperature Unit:</b> F <b>Temperature Location::</b> ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-20-2020 14:46:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-20-2020 14:46:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.3	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-20-2020 14:46:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-20-2020 14:46:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

**1. Lab Panel:**

Date	Location	User	Value	Reason
Aug-20-2020 14:47:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Aug-20-2020 14:47:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Aug-20-2020 14:47:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Aug-20-2020 14:47:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Aug-20-2020 14:47:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Aug-20-2020 14:47:09 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

(US & Canada)		(b) (4), (b) (6)	<b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable
---------------	--	------------------	---

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-20-2020 14:47:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-20-2020 14:47:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-20-2020 14:47:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Aug-20-2020 14:47:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** RANDOMIZATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

**1. Randomization Date :**

Date	Location	User	Value	Reason
Aug-20-2020 14:47:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/20/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-20-2020 14:47:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 59449	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Aug-20-2020 15:14:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-20-2020 15:14:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-20-2020 15:14:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-20-2020 15:14:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/20/2020	Transcription Error
Aug-20-2020 15:14:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Aug-20-2020 15:14:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-20-2020 15:14:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of Assessment is a future date relative to when it was entered. Please correct.

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (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: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Aug-20-2020 15:14:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/28/2020	Initial Entry
--	-----------------	---------------------	---	---------------

5.a

Date	Location	User	Value	Reason
Aug-20-2020 15:14:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BP57RX</b>	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-20-2020 15:14:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP57RX	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-20-2020 15:15:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BP57RY</b>	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-20-2020 15:15:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP57RY	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-20-2020 15:15:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BP57RZ</b>	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (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: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

5.c Sample ID

Date	Location	User	Value	Reason
Aug-20-2020 15:15:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP57RZ	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-21-2020 09:38:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPRSGM	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 09:38:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPRSGM	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-21-2020 09:38:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPRSGN	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 09:38:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPRSGN	Initial Entry

5.f

Date	Location	User	Value	Reason
Aug-21-2020 09:38:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPRSGP	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (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:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

**5.f Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Aug-21-2020 09:38:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPRSGP	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Aug-20-2020 15:16:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-20-2020 15:16:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-21-2020 09:38:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-20-2020 23:55:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-20-2020 15:16:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-20-2020 15:16:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/20/2020	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (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:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

**5.a**

Date	Location	User	Value	Reason
Aug-21-2020 09:38:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP57P6	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-21-2020 09:38:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP57P6	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1136

Subject No: 11361029

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1136) Clinical Research Center of Nevada

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Aug-20-2020 14:48:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Aug-20-2020 14:48:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-20-2020 14:48:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Aug-20-2020 14:48:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/20/2020 14:02	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-20-2020 14:48:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Aug-20-2020 14:48:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1136

Subject No: 11361029

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1136) Clinical Research Center of Nevada

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

7. Route:

Date	Location	User	Value	Reason
Aug-20-2020 14:48:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-20-2020 14:48:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-20-2020 14:48:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

**1. Select appropriate response - Reactogenicity diary collection**

Date	Location	User	Value	Reason
Sep-03-2020 04:34:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Data updated.
Sep-02-2020 16:04:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Sep-02-2020 16:04:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES - REACTOGENICITY E- DIARY COLLECTED FOR THI S SUBJECT	New Information
Sep-02-2020 01:45:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	eDiary: REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT is 'No' however VAX 1 eDiary records are available for the subject. Please verify and update. Else, confirm in query response appropriately.
Aug-20-2020 14:48:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-18-2020 12:38:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/11/2020	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[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
Sep-23-2020 05:29:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-22-2020 12:43:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Sep-22-2020 12:43:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
Sep-21-2020 07:09:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical query: please complete this page: Thanks

**2.a**

Date	Location	User	Value	Reason
Sep-22-2020 12:43:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> N O	Initial Entry
Sep-22-2020 12:43:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry

**2.a Symptom:**

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Date	Location	User	Value	Reason
Sep-22-2020 12:43:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 12:43:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-22-2020 12:43:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FA TIG UE <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry
Sep-22-2020 12:43:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FA TIG UE <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

2.b Symptom:

Date	Location	User	Value	Reason
Sep-22-2020 12:43:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 12:43:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Oct-28-2020 16:07:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HEADAC HE <b>Were fever or system YES</b> <b>ic symptoms present Ongoing</b> <b>on the last day the S ?</b> <b>ubject Diary was co</b> <b>mpleted?:</b> NO  Stop Date:  Au g/2 8/2 020	New Information
Oct-14-2020 09:00:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HE AD AC HE <b>Were fever or systemic sy NO</b> <b>mptoms present on the las</b> <b>t day the Subject Diary w</b> <b>as completed?:</b>	Changed Information

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 21-Aug-2020 02:52

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

<p>Sep-22-2020 12:43:10 (UTC-08:00) Pacific Time (US &amp; Canada)</p>	<p>ACVOPFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p><b>Data Entry:</b> <b>Symptom::</b> HEADAC HE <b>Were fever or system YES</b> <b>ic symptoms present Ongoing</b> <b>on the last day the S ?</b> <b>ubject Diary was co</b> <b>mpleted?:</b> NO  Stop Date:  Au g/2 3/2 020</p>	<p>Initial Entry</p>
--	------------------------	-----------------------------	---	----------------------

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

2.c Symptom:

Date	Location	User	Value	Reason
Sep-22-2020 12:43:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-28-2020 22:46:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Data updated by site
Oct-28-2020 16:07:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-28-2020 16:07:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing?  NO  Stop Date:  Aug/28/2020	New Information
Oct-15-2020 02:59:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	eDiary RQ1: Thanks for your response. Per diary records, HEADACHE present on Last day however inform entered with 'No' for the same. Please verify and update. If diary entered in error, please enter stop date as last date of diary. Thanks.
Oct-14-2020 09:00:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Oct-14-2020 09:00:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Changed Information
Oct-14-2020 02:05:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	eDiary: Stop Date 23Aug20 for HEADACHE in Inform is before the last eDiary date 26Aug20. Please review and update as appropriate. Thanks.
Sep-22-2020 12:43:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing?  NO  Stop Date:  Aug/23/2020	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-22-2020 12:43:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> CH IL LS  <b>Were fever or systemic sym ptoms present on the last da y the Subject Diary was co mpleted?:</b> NO	Initial Entry
Sep-22-2020 12:43:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> CH IL LS  <b>Were fever or systemic sym ptoms present on the last da y the Subject Diary was co mpleted?:</b>	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

2.d Symptom:

Date	Location	User	Value	Reason
Sep-22-2020 12:43:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 12:43:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Sep-22-2020 12:43:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <b>Symptom::</b> VO MIT ING <b>Were fever or systemic sy mptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry
Sep-22-2020 12:43:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <b>Symptom::</b> VO MIT ING <b>Were fever or systemic sy mptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

2.e Symptom:

Date	Location	User	Value	Reason
Sep-22-2020 12:43:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 12:43:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-22-2020 12:43:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DIA RR HE A <b>Were fever or systemic sy</b> NO <b>mptoms present on the last</b> <b>day the Subject Diary was</b> <b>completed?:</b>	Initial Entry
Sep-22-2020 12:43:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DIA RR HE A <b>Were fever or systemic sy</b> <b>mptoms present on the last</b> <b>day the Subject Diary was</b> <b>completed?:</b>	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

2.f Symptom:

Date	Location	User	Value	Reason
Sep-22-2020 12:43:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 12:43:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-22-2020 12:43:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <b>Symptom::</b> NEW OR WORSE ED MUS CLE PAI N  <b>Were fever or system ic symptoms present on the last day the Su bject Diary was comp leted?:</b> NO	Initial Entry
Sep-22-2020 12:43:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <b>Symptom::</b> NEW OR WORSE ED MUS CLE PAI N  <b>Were fever or system ic symptoms present on the last day the Su bject Diary was comp leted?:</b>	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

2.g Symptom:

Date	Location	User	Value	Reason
Sep-22-2020 12:43:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE NED JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 12:43:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-22-2020 12:43:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED JOI NT PAIN  <b>Were fever or systemi c symptoms present o n the last day the Sub ject Diary was comple ted?:</b> NO	Initial Entry
Sep-22-2020 12:43:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED JOI NT PAIN  <b>Were fever or systemi c symptoms present o n the last day the Sub ject Diary was comple ted?:</b>	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

2.h Symptom:

Date	Location	User	Value	Reason
Sep-22-2020 12:43:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENERD JOINT PA IN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 12:43:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-22-2020 12:43:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-22-2020 12:43:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-22-2020 12:43:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RE DN ESS  <b>Were injection site reaction NO s present on the last day th e Subject Diary was compl eted?:</b>	Initial Entry
Sep-22-2020 12:43:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RE DN	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)



Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

			ESS	
Were injection site reactions present on the last day the Subject Diary was completed?:				

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-22-2020 12:43:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 12:43:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-06-2020 13:59:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction:: SWE LLI NG  Were injection site reactions present on the last day the Subject Diary was completed?: NO	Transcription Error
Sep-22-2020 12:43:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction:: SWELLI NG	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:52

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

			<b>Were injection site re actions present on th e last day the Subject Diary was completed ?:</b>	YES Ongoing ? NO Stop Date: Aug /24/ 202 0	
--	--	--	---	---	--

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-22-2020 12:43:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 04:58:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Data updated by site.
Oct-06-2020 13:59:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-06-2020 13:59:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Transcription Error
Oct-03-2020 06:21:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	eDiary RQ1: Thanks for the response. Per CCG, This CRF is to document findings occurred after conclusion of the diary period. In eDiary, Swelling is not reported on last day 26/Aug/20. Please verify and update appropriately
Oct-01-2020 13:37:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	stop date 8/24/20
Sep-29-2020 23:55:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	eDiary: Per eDiary records, "Swelling occurrence" is not reported on Last day (Day 7) however the last day in Inform

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

				CRF data is entered as 'Yes' for the same. Please verify and update. Else, clarify. Thanks (SDQ)
Sep-22-2020 12:43:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing?  NO  Stop Date:  Aug/24/2020	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-06-2020 13:59:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> PAIN AT INJECTION SITE : T INJECTION SITE  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Transcription Error
Sep-22-2020 12:43:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> PAIN AT INJECTION SITE ion:: NJECTION SITE  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> YES Ongoing?  NO  Stop Date:  Aug/24/2020	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Sep-22-2020 12:43:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-07-2020 04:58:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Data updated by site.
Oct-06-2020 13:59:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-06-2020 13:59:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Transcription Error
Oct-03-2020 06:21:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	eDiary RQ1: Thanks for the response. Per CCG, This CRF is to document findings occurred after conclusion of the diary period. In eDiary, Injection Pain is not reported on last day 26/Aug/20. Please verify and update appropriately
Oct-01-2020 13:37:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	stop date 8/24/20
Sep-29-2020 23:57:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	eDiary: Per eDiary records, "Pain at injection site occurrence" is not reported on Last day (Day 7) however the

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 21-Aug-2020 02:52

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

				last day in Inform CRF data is entered as 'Yes' for the same. Please verify and update. Else, clarify. Thanks(SDQ)
Sep-22-2020 12:43:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing?  NO  Stop Date:  Aug/24/2020	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 15-Sep-2020 21:54

Site No: 1136

Subject No: 11361029

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1136) Clinical Research Center of Nevada

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Sep-18-2020 12:38:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/11/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-18-2020 12:38:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 98.6 <b>Temperature Unit:</b> F <b>Temperature Location::</b> ORAL CAVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-18-2020 12:38:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-18-2020 12:38:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.6	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-18-2020 12:38:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:54

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

Date	Location	User	Value	Reason
Sep-18-2020 12:38:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry



Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-18-2020 12:39:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Sep-18-2020 12:39:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Sep-18-2020 12:39:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Sep-18-2020 12:39:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Sep-18-2020 12:39:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Sep-18-2020 12:39:04 (UTC-08:00) Pacific	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Time (US & Canada)		(b) (4), (b) (6)	<b>Sponsor-Defined Identifier:</b> <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable	
Sep-18-2020 12:38:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> <b>Not Done::</b>	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-18-2020 12:39:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-18-2020 12:38:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-18-2020 12:39:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-18-2020 12:39:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (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: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Sep-18-2020 16:25:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-18-2020 16:25:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-18-2020 16:25:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-18-2020 16:25:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-18-2020 16:25:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/11/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-18-2020 16:25:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP57X5	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (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:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

**5.a Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-18-2020 16:25:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP57X5	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1136

Subject No: 11361029

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1136) Clinical Research Center of Nevada

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-18-2020 12:39:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-18-2020 12:39:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-18-2020 12:39:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-18-2020 12:39:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/11/2020 15:44	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-18-2020 12:39:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Sep-18-2020 12:39:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1136

Subject No: 11361029

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1136) Clinical Research Center of Nevada

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

7. Route:

Date	Location	User	Value	Reason
Sep-18-2020 12:39:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-18-2020 12:39:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 12:39:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> YES	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form Version: 22-Apr-2020 21:02

Site No: 1136

Subject No: 11361029

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1136) Clinical Research Center of Nevada

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

*I. Date of Visit*

Date	Location	User	Value	Reason
Nov-10-2020 13:28:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Nov-10-2020 09:24:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Data has been added
Nov-10-2020 00:18:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	RQ1: Previous response states 'Data has been added to EDC' however no Covid Illness visit reported that corresponds with Illness eDiary response on 05NOV2020. Please update or clarify.
Nov-09-2020 16:33:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Data has been added to EDC
Nov-09-2020 08:23:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Illness eDiary: As per Illness ed diary records, subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 05NOV2020. But there is no COVID Illness visit reported in the database.
Nov-06-2020 14:44:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form Version:** 22-Apr-2020 21:02**Site No:** 1136**Subject No:** 11361029**Generated By:** (b) (4)**Form:** DATE OF VISIT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1136) Clinical Research Center of Nevada**Subject Initials:** ---**Generated Time (GMT):** 19-Apr-2021 21:04

Nov-06-2020 10:42:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Answered	Data has been completed
Oct-29-2020 06:46:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Reissued:Opened	DM1: Thanks for response, however SYMPRDATE form is still not updated. Please amend as appropriate , else clarify.
Oct-28-2020 16:09:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Answered	Data has been completed.
Oct-27-2020 03:51:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Opened	DM: Kindly consider to update missing SYMPRDATE form or else clarify. Thank you.
Oct-26-2020 13:43:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Closed	Response satisfies query
Oct-26-2020 11:43:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	Data has been completed
Oct-26-2020 04:12:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	DM:As per CRF guidelines, the treatment period is defined as 1st vaccination visit through the 1-month post vaccination visit after the 2nd vaccination. Hence, please complete treatment disposition CRF and update date of EOT to match the date the Visit 3.
Oct-20-2020 10:40:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Oct/12/2020	Initial Entry



Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[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
Nov-11-2020 21:57:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed as per site response, updated PD tracker for clinical review
Nov-11-2020 10:25:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	E-diary was not applicable after vaccine #2
Nov-11-2020 01:33:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	PDQ: Vaccination is given, however FORM level comment added as NOT Applicable added on 'Vaccination Symptoms Diary-Symptom Resolved Dates' CRF. Please review and update if e-diary data is available else clarify.
Nov-10-2020 13:46:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-10-2020 13:46:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Nov-06-2020 10:42:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Nov-10-2020 13:49:20 (UTC-08:00) Pacific	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001  
**Visit:** V3\_MONTH1\_POSTVAX2\_L  
**Form Version:** 21-Aug-2020 02:52  
**Site No:** 1136  
**Subject No:** 11361029  
**Generated By:** (b) (4)

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site Name:** (1136) Clinical Research Center of Nevada  
**Subject Initials:** ---  
**Generated Time (GMT):** 19-Apr-2021 21:04

Time (US & Canada)		(b) (4), (b) (6)	<b>Symptom::</b> FEVER <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	
Nov-10-2020 13:47:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FEVER <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Changed Information
Nov-06-2020 10:42:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FEVER <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Nov-06-2020 10:42:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Nov-10-2020 13:49:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-10-2020 13:47:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Nov-06-2020 10:42:01	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

(UTC-08:00) Pacific Time (US & Canada)		(b) (4), (b) (6)	NO	
--	--	------------------	----	--

2.b

Date	Location	User	Value	Reason
Nov-10-2020 13:49:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FATI GUE  <b>Were fever or systemic sy</b> <b>mptoms present on the la</b> <b>st day the Subject Diary</b> <b>was completed?:</b> icabl e	Initial Entry
Nov-10-2020 13:47:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FA TI GU E  <b>Were fever or systemic sy</b> <b>mptoms present on the las</b> <b>t day the Subject Diary wa</b> <b>s completed?:</b>	Changed Information
Nov-06-2020 10:42:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FA TI GU E  <b>Were fever or systemic sy</b> <b>mptoms present on the las</b> <b>t day the Subject Diary wa</b> <b>s completed?:</b> NO	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

2.b Symptom:

Date	Location	User	Value	Reason
Nov-06-2020 10:42:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Nov-10-2020 13:49:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-10-2020 13:47:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Nov-06-2020 10:42:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Nov-10-2020 13:51:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HEA DAC HE  Were fever or systemic sy Not mptoms present on the las Appl t day the Subject Diary w icabl as completed?: e	Initial Entry
Nov-10-2020 13:45:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HE AD AC HE  Were fever or systemic sy mptoms present on the las t day the Subject Diary w as completed?:	Changed Information

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

<p>Nov-10-2020 09:52:16 (UTC-08:00) Pacific Time (US &amp; Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p><b>Data Entry:</b> <b>Symptom::</b> HEADAC HE <b>Were fever or system YES</b> <b>ic symptoms present Ongoing</b> <b>on the last day the S ?</b> <b>ubject Diary was co</b> <b>mpleted?:</b> NO  Stop Date:  Au g/2 8/2 020</p>	<p>Initial Entry</p>
<p>Nov-10-2020 09:25:37 (UTC-08:00) Pacific Time (US &amp; Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p><b>Data Entry:</b> <b>Symptom::</b> HE AD AC HE  <b>Were fever or systemic sy</b> <b>mptoms present on the las</b> <b>t day the Subject Diary w</b> <b>as completed?:</b></p>	<p>Changed Information</p>
<p>Nov-06-2020 10:42:01 (UTC-08:00) Pacific Time (US &amp; Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p><b>Data Entry:</b> <b>Symptom::</b> HEADAC HE <b>Were fever or system YES</b> <b>ic symptoms present Ongoing</b> <b>on the last day the S ?</b> <b>ubject Diary was co</b> <b>mpleted?:</b> NO  Stop Date:  Au g/2 8/2 020</p>	<p>Initial Entry</p>

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

2.c Symptom:

Date	Location	User	Value	Reason
Nov-06-2020 10:42:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Nov-11-2020 04:29:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-10-2020 13:51:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-10-2020 13:45:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-10-2020 13:45:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Nov-10-2020 13:31:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	RQ2: There is No ediary information for VAX2 in TrialMAX please remove the data from the entire form and enter a Form LEVEL comment of NOT DONE.
Nov-10-2020 09:52:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing?  NO  Stop Date:  Aug/28/2020	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:52**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1136**Site Name:** (1136) Clinical Research Center of Nevada**Subject No:** 11361029**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 19-Apr-2021 21:04

Nov-10-2020 09:25:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-10-2020 09:25:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Nov-09-2020 23:23:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	RQ1:Thank you for response. However please note 28/Aug/2020 e-diary dta belongs to VAX1 and is correctly reported in V2_VAX2_L visit. Since no diary data is available for VAX2, consider to mark this as Not applicable.
Nov-09-2020 16:34:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The subject was contacted via telephone for the end date clarification. Data is correct as entered
Nov-08-2020 08:37:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	eDiary: eDiary data is not available however Symptom resolved CRF is updated with Yes. Please verify and update as appropriate. Thanks
Nov-06-2020 10:42:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing?  NO  Stop Date:  Aug/28/2020	Initial Entry

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

2.d

Date	Location	User	Value	Reason
Nov-10-2020 13:51:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> CHI LLS  <b>Were fever or systemic sy</b> <b>mptoms present on the la</b> <b>st day the Subject Diary</b> <b>was completed?:</b> Not Appl icabl e	Initial Entry
Nov-10-2020 13:47:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> CH IL LS  <b>Were fever or systemic sy</b> <b>mptoms present on the last</b> <b>day the Subject Diary was</b> <b>completed?:</b>	Changed Information
Nov-06-2020 10:42:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> CH IL LS  <b>Were fever or systemic sy</b> <b>mptoms present on the last</b> <b>day the Subject Diary was</b> <b>completed?:</b> NO	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)



Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

2.d Symptom:

Date	Location	User	Value	Reason
Nov-06-2020 10:42:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Nov-10-2020 13:51:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry
Nov-10-2020 13:47:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Changed Information
Nov-06-2020 10:42:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Nov-10-2020 13:51:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: VO MITI NG  Were fever or systemic s Not ymptoms present on the l Appl ast day the Subject Diary icabl was completed?: e	Initial Entry
Nov-10-2020 13:47:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: VO MIT ING  Were fever or systemic sy mptoms present on the la st day the Subject Diary was completed?:	Changed Information
Nov-06-2020 10:42:01	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

(UTC-08:00) Pacific Time (US & Canada)		(b) (4), (b) (6)	<b>Symptom::</b> VO MIT ING  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO
--	--	------------------	---

2.e Symptom:

Date	Location	User	Value	Reason
Nov-06-2020 10:42:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Nov-10-2020 13:51:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-10-2020 13:47:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Nov-06-2020 10:42:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Nov-10-2020 13:51:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DIA RRH EA  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> Not Applicable	Initial Entry
Nov-10-2020 13:47:57 (UTC-08:00) Pacific	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DIA	Changed Information

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

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

**Form Version:** 21-Aug-2020 02:52

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

Time (US & Canada)		(b) (4), (b) (6)	RR HE A  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	
Nov-06-2020 10:42:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptom:: DIA RR HE A  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

**2.f Symptom:**

Date	Location	User	Value	Reason
Nov-06-2020 10:42:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Nov-10-2020 13:51:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-10-2020 13:47:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Nov-06-2020 10:42:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.g**

Date	Location	User	Value	Reason
Nov-10-2020 13:52:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED MU SCLE PA IN  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> Not Applicable	Initial Entry
Nov-10-2020 13:48:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED MU SCLE PA IN	Changed Information

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
Nov-06-2020 10:42:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED MUSCLE PAIN  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Nov-06-2020 10:42:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE NED MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Nov-10-2020 13:52:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-10-2020 13:48:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Nov-06-2020 10:42:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Nov-10-2020 13:52:13	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

(UTC-08:00) Pacific Time (US & Canada)		(b) (4), (b) (6)	<p><b>Symptom::</b> NEW OR WORSE NED JOINT PAIN</p> <p><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> Not Applicable</p>	
Nov-10-2020 13:48:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p><b>Symptom::</b> NEW OR WORSE NED JOINT PAIN</p> <p><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b></p>	Changed Information
Nov-06-2020 10:42:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p><b>Symptom::</b> NEW OR WORSE NED JOINT PAIN</p> <p><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO</p>	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

2.h Symptom:

Date	Location	User	Value	Reason
Nov-06-2020 10:42:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENERD JOINT P AIN	Initial Entry

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

Date	Location	User	Value	Reason
Nov-10-2020 13:52:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-10-2020 13:48:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Nov-06-2020 10:42:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Nov-10-2020 13:46:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Changed Information
Nov-06-2020 10:42:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Nov-10-2020 13:52:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-10-2020 13:48:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Nov-06-2020 10:42:01	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

(UTC-08:00) Pacific Time (US & Canada)		(b) (4), (b) (6)	LEFT	
--	--	------------------	------	--

5.a

Date	Location	User	Value	Reason
Nov-10-2020 13:52:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RED NES S  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> Not applicable	Initial Entry
Nov-10-2020 13:48:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RE DN ESS  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b>	Changed Information
Nov-06-2020 10:42:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RE DN ESS  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-06-2020 10:42:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)



Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Nov-10-2020 13:52:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-10-2020 13:48:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Nov-06-2020 10:42:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-10-2020 13:52:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> SWE LLIN G  <b>Were injection site reacti</b> Not <b>ons present on the last d</b> Appli <b>ay the Subject Diary was</b> cable <b>completed?:</b>	Initial Entry
Nov-10-2020 13:48:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> SW ELL ING  <b>Were injection site reacti</b> <b>ons present on the last da</b> <b>y the Subject Diary was c</b> <b>ompleted?:</b>	Changed Information
Nov-06-2020 10:42:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> SW ELL ING  <b>Were injection site reacti</b> NO <b>ons present on the last da</b> <b>y the Subject Diary was c</b> <b>ompleted?:</b>	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Nov-06-2020 10:42:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(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
Nov-10-2020 13:52:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry
Nov-10-2020 13:48:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Changed Information
Nov-06-2020 10:42:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-10-2020 13:53:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction PAIN A :: T INJE CTION SITE  Were injection site rea Not Ap ctions present on the l plicable ast day the Subject Di ary was completed?:	Initial Entry
Nov-10-2020 13:49:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction PAIN A :: T INJE CTION SITE  Were injection site rea ctions present on the l ast day the Subject Di ary was completed?:	Changed Information

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Nov-06-2020 10:42:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction</b> PAIN A :: T INJE CTION SITE  <b>Were injection site rea</b> NO <b>ctions present on the l</b> <b>ast day the Subject Di</b> <b>ary was completed?:</b>	Initial Entry
---	-----------------	---------------------	---	---------------

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Nov-06-2020 10:42:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Nov-10-2020 13:53:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-10-2020 13:49:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Nov-06-2020 10:42:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Oct-20-2020 10:49:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-20-2020 10:49:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-20-2020 10:50:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-20-2020 10:49:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-20-2020 10:49:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/12/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-20-2020 10:50:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BM91MZ	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

5.a Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 10:50:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM91MZ	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-20-2020 10:50:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BM91N0	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 10:50:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM91N0	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-20-2020 10:50:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BM91N1	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 10:50:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BM91N1	Initial Entry

5.d

Date	Location	User	Value	Reason
Feb-09-2021 11:42:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPRSL0	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

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

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

**5.d Sample ID**

Date	Location	User	Value	Reason
Feb-09-2021 11:42:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPRSL0	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Feb-09-2021 11:44:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPRSL1	Initial Entry

**5.e Sample ID**

Date	Location	User	Value	Reason
Feb-09-2021 11:44:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPRSL1	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Mar-10-2021 08:13:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/10/2021	Initial Entry

Header Text: c4591001

Visit: V4\_MONTH6\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Mar-10-2021 08:13:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-10-2021 08:13:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-10-2021 14:42:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-10-2021 08:13:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-10-2021 08:13:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Mar/10/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-10-2021 14:42:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP586T	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)



Header Text: c4591001

Visit: V4\_MONTH6\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

5.a Sample ID

Date	Location	User	Value	Reason
Mar-10-2021 14:42:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP586T	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-10-2021 14:42:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP586V	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-10-2021 14:42:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP586V	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-10-2021 14:43:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP586W	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-10-2021 14:43:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP586W	Initial Entry

5.d

Date	Location	User	Value	Reason
Mar-10-2021 14:43:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPRSWT	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

**5.d Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Mar-10-2021 14:43:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPRSWT	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

**I. Date of Visit**

Date	Location	User	Value	Reason
Nov-10-2020 12:41:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Nov-10-2020 12:41:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-10-2020 09:09:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Deleted	Close Auto Query
Nov-10-2020 09:05:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Nov-10-2020 09:05:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Nov-10-2020 09:05:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/9/2020	Transcription Error
Nov-10-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Nov-10-2020 09:01:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Data has been updated
Nov-10-2020 04:27:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM: Kindly review and complete 'Health Care Utilization, Microbiology

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

				Specimen, Illness Details form' at this visit. Thank you.
Nov-09-2020 21:49:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Nov-09-2020 21:13:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Nov-09-2020 16:30:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Nov-09-2020 16:30:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Nov-09-2020 16:30:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/9/2020	Initial Entry

**2. Erroneous Visit**

Date	Location	User	Value	Reason
------	----------	------	-------	--------

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Nov/09/2020

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

Mar-08-2021 08:46:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-01-2021 14:12:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	COVID_A1 CONV visit not done. Site error.
Mar-01-2021 06:11:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	COVID_A1 CONV visit expected, but not performed. Pending confirmation if still expected.

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

Date	Location	User	Value	Reason
Nov-09-2020 16:30:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1136**Subject No:** 11361029**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1136) Clinical Research Center of Nevada**Subject Initials:** ---**Generated Time (GMT):** 19-Apr-2021 21:04[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Nov-10-2020 09:05:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-10-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of assessment is not same as Date Visit. Please check and correct.
Nov-10-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/9/2020	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Nov-10-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/4/2020	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Feb-17-2021 00:58:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Updated per query
Feb-16-2021 14:26:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-16-2021 14:26:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Symptom Resolved:  Nov/19/2020	New Information
Feb-15-2021 06:09:28 (UTC-08:00) Pacific	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please confirm the symptoms are still

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Time (US & Canada)		(b) (4), (b) (6)		ongoing for this COVID illness. If all symptoms for this illness are resolved; please update the Last Symptoms Resolved Date else clarify.
Nov-10-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.a**

Date	Location	User	Value	Reason
Nov-10-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b> NO	Initial Entry

**4.a Symptoms:**

Date	Location	User	Value	Reason
Nov-10-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

**4.a Was symptom present?**

Date	Location	User	Value	Reason
Nov-10-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.b**

Date	Location	User	Value	Reason
Nov-10-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED COUGH <b>Symptom Present:</b> NO	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1136**Subject No:** 11361029**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1136) Clinical Research Center of Nevada**Subject Initials:** ---**Generated Time (GMT):** 19-Apr-2021 21:04**4.b Symptoms:**

Date	Location	User	Value	Reason
Nov-10-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED COUGH	Initial Entry

**4.b Was symptom present?**

Date	Location	User	Value	Reason
Nov-10-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.c**

Date	Location	User	Value	Reason
Nov-10-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom:</b> NEW OR INCREASED SHORTNESS OF BREATH <b>Symptom Present:</b> NO	Initial Entry

**4.c Symptoms:**

Date	Location	User	Value	Reason
Nov-10-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

**4.c Was symptom present?**

Date	Location	User	Value	Reason
Nov-10-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.d**

Date	Location	User	Value	Reason
------	----------	------	-------	--------



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Nov-10-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS <b>Symptom Present:</b> NO	Initial Entry
---	-----------------	---------------------	---	---------------

4.d Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Nov-10-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom</b> NEW OR INCREAS <b>s:</b> ED MUSCLE PAIN <b>Symptom</b> NO <b>Present:</b>	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED MUSCL E PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.f

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Date	Location	User	Value	Reason
Nov-10-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms NEW LOSS OF TAS : TE OR SMELL <b>Symptom</b> NO <b>Present:</b>	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW LOSS OF TASTE OR SME LL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Nov-10-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom</b> NEW OR INCREAS s: ED SORE THROAT <b>Symptom</b> YES <b>Present:</b>	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

4.g Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SORE T HROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Nov-10-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> DIARRHEA <b>Symptom Present:</b> NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Nov-10-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITING <b>Symptom Present:</b> NO	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

4.i Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-10-2020 09:06:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms - Other HEADACH : E	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Nov-10-2020 09:06:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> HEADACHE	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-10-2020 09:06:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms - O SINUS CONGE ther: STION	Initial Entry

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Nov-10-2020 09:06:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> SINUS CONGESTION	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Nov/09/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Nov-10-2020 09:07:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Nov-10-2020 09:07:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Nov-10-2020 09:07:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Nov-10-2020 09:07:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Nov-10-2020 09:07:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Nov-10-2020 09:07:35 (UTC-08:00) Pacific	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History  
on Nov/09/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

Time (US & Canada)		(b) (4), (b) (6)	
--------------------	--	------------------	--

**7. Test Result:**

Date	Location	User	Value	Reason
Nov-10-2020 09:07:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**8. Comments/Findings/Details:**

Date	Location	User	Value	Reason
Nov-10-2020 09:07:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**9. Trade Name Other, Specify:**

Date	Location	User	Value	Reason
Nov-10-2020 09:07:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Nov-10-2020 09:08:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-10-2020 09:08:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-10-2020 09:08:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Nov-10-2020 09:08:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SUBJECT CAME INTO THE SI TE FOR SWAB COLLECTION	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Nov-10-2020 09:09:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-10-2020 09:09:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-10-2020 15:51:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-10-2020 12:40:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-10-2020 09:09:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-10-2020 09:09:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/9/2020	Initial Entry

5.a

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

Date	Location	User	Value	Reason
Nov-10-2020 15:51:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRFWTR	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Nov-10-2020 15:51:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRFWTR	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/09/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

**1.a**

Date	Location	User	Value	Reason
Nov-10-2020 09:10:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIALIST <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

**1.a Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Nov-10-2020 09:10:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SPECIALIST	Initial Entry

**1.a Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Nov-10-2020 09:10:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**1.b**

Date	Location	User	Value	Reason
Nov-10-2020 09:10:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENCY ROOM <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/09/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-10-2020 09:10:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

***1.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-10-2020 09:10:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.c***

Date	Location	User	Value	Reason
Nov-10-2020 09:10:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

***1.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-10-2020 09:10:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

***1.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-10-2020 09:10:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.d***

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/09/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Nov-10-2020 09:10:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner</b> URGENT : CARE <b>Occurrence of Visits</b> NO <b>or Contacts:</b>	Initial Entry
---	-----------------	---------------------	--	---------------

***1.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-10-2020 09:10:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> URGENT CARE	Initial Entry

***1.d Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-10-2020 09:10:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.e***

Date	Location	User	Value	Reason
Nov-10-2020 09:10:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE CONSULTATION <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/09/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-10-2020 09:10:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> TELEPHONE CONSULTATION	Initial Entry

***1.e Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-10-2020 09:10:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.f***

Date	Location	User	Value	Reason
Nov-10-2020 09:10:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTH ER <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

***1.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-10-2020 09:10:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

***1.f Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-10-2020 09:10:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-10-2020 09:10:05 (UTC-08:00) Pacific	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
on Nov/09/2020

**Form Version:** 10-Oct-2020 15:59

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

Time (US & Canada)	(b) (4), (b) (6)
--------------------	------------------

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: RESPIRATORY TREATMENT - eCRF Audit Trail History on Nov/09/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Nov-12-2020 15:57:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Nov-12-2020 15:57:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Nov-12-2020 16:56:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-12-2020 15:57:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Nov-12-2020 15:57:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Nov-12-2020 09:37:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Clin: Please use FORM LEVEL comment instead of ITEM LEVEL comment as per CRF CRs Section 4.10.
Nov-12-2020 08:59:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: RESPIRATORY TREATMENT - eCRF Audit Trail History on Nov/09/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Nov-12-2020 08:58:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-11-2020 17:49:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Query: If no respiratory treatment given, please enter FORM LEVEL comment of Not Applicable.
Nov-10-2020 09:10:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Nov-12-2020 15:57:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Nov-12-2020 15:57:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Nov-12-2020 08:59:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-10-2020 09:10:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Nov-12-2020 15:57:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Nov-10-2020 09:12:58 (UTC-08:00) Pacific	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History  
on Nov/09/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

Time (US & Canada)		(b) (4), (b) (6)		
Nov-10-2020 09:11:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - eCRF Audit Trail History  
on Nov/09/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Nov-10-2020 09:11:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID-19 ILLNESS	Initial Entry

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

Date	Location	User	Value	Reason
Nov-10-2020 09:11:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Nov-10-2020 09:13:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-10-2020 09:13:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Changed Information
Nov-10-2020 09:11:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Per CRF CRs Section 8.33.5, please enter worst toxicity grade (1 to 5) as it relates to reported symptom(s) on SOD CRF. Please review and update as appropriate.
Nov-10-2020 09:11:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Audit Trail  
on Nov/09/2020

**Form Version:** 17-Jul-2020 21:55

**Form Status:**

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-10-2020 09:14:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Nov/09/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Nov-12-2020 08:58:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-12-2020 08:57:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Changed Information
Nov-10-2020 09:14:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE COVID-19 ILLNESS	Initial Entry

**2. Subcategory of Clinical Event:**

Date	Location	User	Value	Reason
Nov-12-2020 08:58:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-10-2020 09:13:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Was a diagnosis obtained?**

Date	Location	User	Value	Reason
Nov-12-2020 09:32:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-12-2020 08:58:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-12-2020 08:57:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Nov-12-2020 08:57:44 (UTC-08:00) Pacific	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Nov/09/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Time (US & Canada)		(b) (4), (b) (6)		
Nov-11-2020 17:47:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical Query: Per CRF CRs Section 8.31, this CRF should only be completed if subject had significant renal, hepatic or neurological dysfunction. If not, please enter FORM LEVEL comment of Not Applicable.
Nov-10-2020 12:40:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-10-2020 09:24:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	No diagnosis was obtained. Data is correct as entered
Nov-10-2020 09:14:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Was a diagnosis obtained?" is No. Please review and update as appropriate.
Nov-10-2020 09:14:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-12-2020 08:58:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-10-2020 09:14:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

			Not Done::	Not Done
			Lab Normal Range:	Not Done

5.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done <b>Test::</b> Not Done <b>Result::</b> Not Done <b>Not Done::</b> Not Done <b>Lab Normal Range:</b> Not Done	Initial Entry



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

5.b Sponsor ID:

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

			<b>Test::</b>	Not Done	
			<b>Result::</b>	Not Done	
			<b>Not Done::</b>	Not Done	
			<b>Lab Normal Range:</b>	Not Done	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

5.c Sponsor ID:

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

			<b>Test::</b>	Not Done	
			<b>Result::</b>	Not Done	
			<b>Not Done::</b>	Not Done	
			<b>Lab Normal Range:</b>	Not Done	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

5.d Sponsor ID:

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

			<b>Test::</b>	Not Done	
			<b>Result::</b>	Not Done	
			<b>Not Done::</b>	Not Done	
			<b>Lab Normal Range:</b>	Not Done	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

5.e Sponsor ID:

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.f

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

			<b>Test::</b>	Not Done	
			<b>Result::</b>	Not Done	
			<b>Not Done::</b>	Not Done	
			<b>Lab Normal Range:</b>	Not Done	



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

5.f Sponsor ID:

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

			<b>Test::</b>	Not Done	
			<b>Result::</b>	Not Done	
			<b>Not Done::</b>	Not Done	
			<b>Lab Normal Range:</b>	Not Done	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

5.g Sponsor ID:

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Nov-10-2020 09:16:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

**1. Lab Panel:**

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done <b>Test::</b> Not Done <b>Result::</b> Not Done	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

			Not Done::	Not Done
			Lab Normal Range:	Not Done

5.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done <b>Test:</b> Not Done <b>Result:</b> Not Done <b>Not Done:</b> Not Done <b>Lab Normal Range:</b> Not Done	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

5.b Sponsor ID:

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

			<b>Test::</b>	Not Done	
			<b>Result::</b>	Not Done	
			<b>Not Done::</b>	Not Done	
			<b>Lab Normal Range:</b>	Not Done	



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

5.c Sponsor ID:

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

			<b>Test::</b>	Not Done	
			<b>Result::</b>	Not Done	
			<b>Not Done::</b>	Not Done	
			<b>Lab Normal Range:</b>	Not Done	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

5.d Sponsor ID:

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

			<b>Test::</b>	Not Done	
				ne	
			<b>Result::</b>	Not Done	
				ne	
			<b>Not Done::</b>	Not Done	
				ne	
			<b>Lab Normal Range:</b>	Not Done	
				ne	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

5.e Sponsor ID:

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.f

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

			<b>Test::</b>	Not Done	
			<b>Result::</b>	Not Done	
			<b>Not Done::</b>	Not Done	
			<b>Lab Normal Range:</b>	Not Done	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

5.f Sponsor ID:

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

			<b>Test::</b>	Not Done	
				ne	
			<b>Result::</b>	Not Done	
				ne	
			<b>Not Done::</b>	Not Done	
				ne	
			<b>Lab Normal Range:</b>	Not Done	
				ne	



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

5.g Sponsor ID:

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.h

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

			<b>Test::</b>	Not Done	
			<b>Result::</b>	Not Done	
			<b>Not Done::</b>	Not Done	
			<b>Lab Normal Range:</b>	Not Done	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

5.h Sponsor ID:

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.i

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

			<b>Test::</b>	Not Done	
			<b>Result::</b>	Not Done	
			<b>Not Done::</b>	Not Done	
			<b>Lab Normal Range:</b>	Not Done	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

**5.i Sponsor ID:**

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.i Test:**

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.i Result:**

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.i Not Done:**

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.i LNMT**

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.j**

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined Ident Not Do	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

			<b>ifier:</b>	ne	
			<b>Test::</b>	Not Done	
				ne	
			<b>Result::</b>	Not Done	
				ne	
			<b>Not Done::</b>	Not Done	
				ne	
			<b>Lab Normal Range:</b>	Not Done	
				ne	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

**5.j Sponsor ID:**

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.j Test:**

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.j Result:**

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.j Not Done:**

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.j LNMT**

Date	Location	User	Value	Reason
Nov-10-2020 09:17:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail  
on Nov/09/2020

**Form Version:** 30-Jul-2020 21:27

**Form Status:**

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-10-2020 09:21:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Created	



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Nov/09/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Nov-10-2020 09:21:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/9/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Nov-10-2020 09:21:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Systolic::</b> 11 2 <b>Diastolic::</b> 84 <b>Respiratory Rate in respirat</b> 18 <b>ions/minute:</b> <b>Heart Rate in beats/minute:</b> 72	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Nov-10-2020 09:21:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Systolic:**

Date	Location	User	Value	Reason
Nov-10-2020 09:21:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 112	Initial Entry

**2.a Diastolic:**

Date	Location	User	Value	Reason
Nov-10-2020 09:21:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 84	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History  
on Nov/09/2020

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

**2.a Respiratory Rate in respirations/minute:**

Date	Location	User	Value	Reason
Nov-10-2020 09:21:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 18	Initial Entry

**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Nov-10-2020 09:21:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 72	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail  
on Nov/09/2020

**Form Version:** 30-Jul-2020 21:28

**Form Status:**

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Date	Location	User	Value	Reason
Nov-10-2020 09:22:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Nov-10-2020 09:22:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/9/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Nov-10-2020 09:22:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Oxygen Saturation:</b> 97.0	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Nov-10-2020 09:22:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a SPO2 Pulse Oximetry %**

Date	Location	User	Value	Reason
Nov-10-2020 09:22:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 97.0	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History on Nov/09/2020

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

**1. Date Time of Assessment:**

Date	Location	User	Value	Reason
Nov-10-2020 09:22:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Arterial Blood Gases PaO2 (mmHg):**

Date	Location	User	Value	Reason
Nov-10-2020 09:22:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. FiO2 (Fraction of Inhaled Oxygen):**

Date	Location	User	Value	Reason
Nov-10-2020 09:22:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/09/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1136

Site Name: (1136) Clinical Research Center of Nevada

Subject No: 11361029

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Nov-10-2020 09:22:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Nov-10-2020 09:22:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Nov-10-2020 09:22:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Medication:**

*Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).*

Date	Location	User	Value	Reason
Nov-10-2020 09:22:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Nov-10-2020 09:22:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**6. Ongoing?**

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Nov/09/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF  
Audit Trail History

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

Date	Location	User	Value	Reason
Nov-10-2020 09:22:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Not Done	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** IMAGING - eCRF Audit Trail History  
on Nov/09/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

**1. Date of Assessment:**

Date	Location	User	Value	Reason
Nov-10-2020 09:22:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Not Done	Initial Entry

**2. Location of Assessment:**

Date	Location	User	Value	Reason
Nov-10-2020 09:22:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Not Done	Initial Entry

**3. Type of Imaging Exam:**

Date	Location	User	Value	Reason
Nov-10-2020 09:22:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Not Done	Initial Entry

**4. Assessment:**

Date	Location	User	Value	Reason
Nov-10-2020 09:22:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Not Done	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)



**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Oct-26-2020 11:41:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/12/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-26-2020 11:41:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-26-2020 11:41:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-10-2021 09:14:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1136

Subject No: 11361029

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1136) Clinical Research Center of Nevada

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Mar-10-2021 09:14:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Mar-10-2021 09:14:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-12-2021 08:09:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-12-2021 08:05:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The subject was not hospitalized for AE.
Mar-12-2021 05:04:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	clinical: thanks, pls confirm subject not hospitalized for AE.
Mar-11-2021 15:15:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Mar-11-2021 15:15:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> worsening of intermittent seizure s	Changed Information
Mar-11-2021 09:07:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: given prolonged duration of AE pls confirm subject not hospitalized. Pls clarify if subject having intermittent

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1136

Subject No: 11361029

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1136) Clinical Research Center of Nevada

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

				seizures during this entire period. Thanks
Mar-10-2021 09:14:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> worsening of seizures	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-10-2021 09:14:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/1/2020 00:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-10-2021 09:14:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Jan/25/2021 00:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-10-2021 09:14:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Mar-10-2021 09:14:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1136

Subject No: 11361029

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete

Site Name: (1136) Clinical Research Center of Nevada

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

**If Yes, record the type of medication error on the Medication Error Log.**

Date	Location	User	Value	Reason
Mar-10-2021 09:14:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Mar-10-2021 09:14:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment( s), this event is due to:  OTHER  <i>If Other, specify:</i>  Med Hx of epilepsy	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Mar-10-2021 09:14:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Mar-10-2021 09:14:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Mar-10-2021 09:14:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**13. What was the outcome of this adverse event?:**

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

Date	Location	User	Value	Reason
Mar-10-2021 09:14:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

*14. Did the adverse event cause the subject to be discontinued from the study?*

Date	Location	User	Value	Reason
Mar-10-2021 09:14:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

*I. Date of Visit*

Date	Location	User	Value	Reason
Feb-25-2021 10:13:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/14/2021	Transcription Error
Jan-19-2021 10:20:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/15/2021	Initial Entry

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form Version:** 10-Dec-2020 02:25

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail  
History

**Form Status:** Data Complete, Frozen

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

**1. Select appropriate response - Is participant willing to return for Vaccination 3?**

Date	Location	User	Value	Reason
Mar-08-2021 08:53:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return f or Vaccination 3 Participant is:  eligible and NOT confirmed to have received only placeb o at Vaccination 1/2	Changed Information
Jan-22-2021 06:10:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-21-2021 12:14:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Jan-21-2021 09:40:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - The response indicates participant was potentially unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please confirm and update accordingly.
Jan-19-2021 10:20:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is NOT willing to re turn for Vaccination 3 OR other wise not eligible	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)



**Header Text:** c4591001**Visit:** Disposition - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1136**Subject No:** 11361029**Generated By:** (b) (4)**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1136) Clinical Research Center of Nevada**Subject Initials:** ---**Generated Time (GMT):** 19-Apr-2021 21:04[Back to Form](#)**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-26-2021 06:26:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Response satisfies query
Feb-25-2021 10:13:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	Changed data per query
Feb-23-2021 06:38:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW7352272;Date Treatment Unblinded should be equal to or after DOV in REVAX CONTACT visit when Reason is ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION.Please review and update as appropriate.
Jan-21-2021 12:13:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : Jan/14 /2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Mar-08-2021 12:24:30 (UTC-08:00) Pacific Time (US &	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Response satisfies query

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1136

Subject No: 11361029

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1136) Clinical Research Center of Nevada

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Canada)				
Mar-08-2021 09:14:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: An swere d	Changed data per query
Mar-08-2021 07:25:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Rivkah Rosen (b) (4) [Redacted]	Query 1: Rei ssued: Opene d	DM: Form has been unfrozen. If active treatment received, data should be as follows: FURTHER VACCINATION CONFIRMATION = 'Participant is willing to return for Vaccination 3' & select 'Eligible and NOT confirmed to have received only placebo at Vax 1/2'.
Mar-05-2021 11:05:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: An swere d	The subject received active IP during study participation and thus is not eligible to return for vaccination.
Mar-02-2021 06:26:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Rei ssued: Opene d	Please note that if reason for Unblinding is ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION then "Participant is willing to return for Vaccination 3" should be selected on the FURTHER VACCINATION CONFIRMATION form. Please review and update accordingly
Mar-01-2021 10:43:55	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: An	Original value is correct

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1136

Subject No: 11361029

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1136) Clinical Research Center of Nevada

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

(UTC-08:00) Pacific Time (US & Canada)			swere d	
Feb-25-2021 21:25:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Rei ssued: Opene d	DM : Thanks for response. However, "Participant is willing to return for Vaccination 3" is still not selected in the REVAX CONF CRF. Please refer CCG section 8.58.1. Please update or clarify.
Feb-25-2021 10:15:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: An swere d	Changed data per query
Feb-25-2021 05:00:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Rei ssued: Opene d	DM: If active treatment received, data should be as follows: FURTHER VACCINATION CONFIRMATION = 'Participant is willing to return for Vaccination 3' & select 'Eligible and NOT confirmed to have received only placebo at Vaccination 1/2'.
Feb-24-2021 09:50:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: An swere d	Subj is ineligible as indicated.
Feb-22-2021 11:49:00 (UTC-08:00) Pacific Time (US &	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW7350234;Primary Reason for Unblinding is "ASSESS ELIGIBILITY FOR ADDITIONAL

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

Canada)				VACCINATION", but "Participant is willing to return for Vaccination 3" is not selected in the Further Vaccination Confirmation CRF. Please review and update as appropriate.
Jan-21-2021 12:13:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** WITHDRAWAL OF CONSENT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

**1. Withdrawal of Consent Date :**

Date	Location	User	Value	Reason
Jan-21-2021 12:13:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** DEATH DETAILS CODED - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

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

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Jan-21-2021 12:13:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1136

**Subject No:** 11361029

**Generated By:** (b) (4)

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

**1. Subject Status**

Date	Location	User	Value	Reason
Oct-26-2020 11:41:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-20-2020 14:47:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-20-2020 14:41:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Oct-26-2020 11:41:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/12/2020	Initial Entry
Aug-20-2020 14:47:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/20/2020	Initial Entry
Aug-20-2020 14:41:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/20/2020	Initial Entry

090177e196d89033\Final\Final On: 22-Apr-2021 02:14 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Verified

**Site No:** 1136

**Site Name:** (1136) Clinical Research Center of Nevada

**Subject No:** 11361029

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

[Back to Form](#)

*1. Casebook Signature*

Date	Location	User	Value	Reason
Nov-16-2020 11:59:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Click Here to Enable	Initial Entry