

**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:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** MAIN INFORMED CONSENT

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/9/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10481104]
2.	Birth Date:	(b) (6)/1963
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

**Header Text:** c4591001

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

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** DATE OF VISIT

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

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

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1048) The Pain Center of Arizona

**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 _____
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**Exclusion Criteria Met**

2.	Description of Exclusion Criterion Met	Not Applicable _____
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**Header Text:** c4591001

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

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation /Death	Sep/9/2020
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:** 1048

**Subject No:** 10481104

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1048) The Pain Center of Arizona

**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:	[Immune mediated thyroiditis]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Migraine]
	Start Date:	UNK/UNK/1995
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hysterectomy]
	Start Date:	UNK/UNK/2011
	Ongoing:	NO End Date: UNK/UNK/2011

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

**Form:** VITAL SIGNS - BASELINE

**Form Version:** 21-Aug-2020 02:51

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/9/2020
2.	Weight:	[143.0]
3.	Unit:	LB
4.	Height:	[65.0]
5.	Unit:	in
6.	Body Mass Index:	[23.8]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[97.4]
	Unit:	F
	Temperature Location:	ORAL CAVITY



**Header Text:** c4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Lab Urinalysis**

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

**Lab Result**

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

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** RANDOMIZATION

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Sep/9/2020
2.	Randomization Number:	[255038]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**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	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/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	[BP3LNK]
5.b	Sample ID	[BP3LNL]
5.c	Sample ID	[BP3LNM]
5.d	Sample ID	[BPL2M3]
5.e	Sample ID	[BPL2M4]

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**Header Text:** c4591001

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

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

**Site No:** 1048

**Subject No:** 10481104

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

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

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

**Site Name:** (1048) The Pain Center of Arizona

**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/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	[BP3LRH]
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090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** VACCINATION

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

**Site Name:** (1048) The Pain Center of Arizona

**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/9/2020 15:49
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

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

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

**Visit:** V2\_VAX2\_L

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** DATE OF VISIT

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/30/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/30/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[97.9]
	Unit:	F
	Temperature Location:	ORAL CAVITY



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1048) The Pain Center of Arizona

**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>

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1048

**Subject No:** 10481104

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

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

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

**Site Name:** (1048) The Pain Center of Arizona

**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/30/2020
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	[BP3LWK]
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090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** VACCINATION

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

**Site Name:** (1048) The Pain Center of Arizona

**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/30/2020 13:31
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

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

**Form:** DATE OF VISIT

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**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/4/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**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	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/4/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPVSLD]
5.b	Sample ID	[BS69G3]
5.c	Sample ID	[BS69G2]

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

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

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**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/12/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_A
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

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

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**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/12/2020
2.	Date of First Symptom Started:	Nov/11/2020
3.	Symptoms Ongoing?	NO
	Date of Last Symptom Resolved:	Dec/16/2020

**Symptoms**

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

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

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

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

4.i	Symptoms:	VOMITING
	Was symptom present?	NO

**Symptoms - Other**

5.	Symptoms - Other Text:	[ ]
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**Header Text:** c4591001

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

**Form:** MICROBIOLOGY SPECIMEN

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**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.	Nov/12/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**Form:** MICROBIOLOGY SPECIMEN

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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**Microbiology Specimen**

1.	Actual Date of Collection:	Nov/12/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	POSITIVE
8.	Comments/Findings/Details:	[ ]
9.	Trade Name Other, Specify:	[BD Veritor SARS-CoV-2 Rapid Detection Kit - CLIA-c]

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

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

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**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?	YES Date of Collection: Nov/13/2020
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	[ ]
5.b	Sample ID	[RR03268]

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

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

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**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?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[HOME SWAB COLLECTED AND SHIPPED]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 10-Oct-2020 15:59

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**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:	YES Number of Visits or Contacts: [1]
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**

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 10-Oct-2020 15:59

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

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

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**Form:** RESPIRATORY TREATMENT

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

**Form Status:** Not Started

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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**Respiratory Treatment**

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



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**Form:** ILLNESS DETAILS

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**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?	YES Respiratory Illness Diagnosis: [COVID - 19]  Date of Diagnosis: Nov/12/2020
3.	Toxicity Grade:	2

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**Header Text:** c4591001

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

**Form:** ILLNESS DETAILS - SEVERE

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**Form:** ILLNESS DETAILS - SEVERE

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

**Form Status:** Not Started

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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**Illness Details**

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

**Header Text:** c4591001

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

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**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.					Sponsor-Defined Identifier	Test:	Result:	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Not Started

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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**Lab Chemistry Details**

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

**Lab Result**

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

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**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.					Sponsor-Defined Identifier	Test:	Result:	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Not Started

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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**Laboratory Data Hematology**

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

**Lab Result**

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

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

**Form:** VITAL SIGNS - COVID

**Form Version:** 21-Aug-2020 02:50

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

#	Date:	Vital Signs Details			Form Instance
1.		Record Identifier:	Systolic:	Diastolic:	<a href="#">Repeating Pages</a>



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**Form:** VITAL SIGNS - COVID

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Not Started

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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**Vital Signs**

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

**Vital Signs Details**

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

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**Header Text:** c4591001

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

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

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

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

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Not Started

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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**Vital Signs**

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

**Vital Signs Details**

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[ ]

**Header Text:** c4591001

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

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

#	Date Time of Assessment	Arterial Blood Gases PaO <sub>2</sub>	FiO <sub>2</sub> (Fraction of Inhaled Oxygen)	Form Instance
1.				<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**Form:** OXYGENATION PARAMETERS

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

**Form Status:** Not Started

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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**Oxygenation Parameters**

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

**Header Text:** c4591001

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

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**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:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

**Form Status:** Not Started

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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**Concomitant Medications**

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

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

**Form:** IMAGING

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

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



**Header Text:** c4591001

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

**Form:** IMAGING

Visit on Nov/12/2020

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

**Form Status:** Not Started

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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**Imaging**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Dec/16/2020

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

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**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	Dec/16/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Dec/16/2020

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

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

**Site Name:** (1048) The Pain Center of Arizona

**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: Dec/16/2020
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	[BPVSLX]
5.b	Sample ID	[BS69H2]
5.c	Sample ID	[BS69H3]

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Nov/12/2020

**Form:** DATE OF VISIT

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**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/12/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Nov/12/2020

**Form:** UNPLANNED VISIT

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Nov/12/2020

**Form:** CONTACT OUTCOME - UNPLANNED

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT	
2.	Was contact made?	YES Date of Contact: Nov/12/2020  Contact Outcome: VISIT ARRANGED	
3.	Comments:	Not Applicable <hr/> [ ]	<a href="#">Comments</a>

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Nov/12/2020

**Form:** VITAL SIGNS - TEMP

**Form Version:** 10-Oct-2020 16:01

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Nov/12/2020
----	-------	-------------

**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[100.5]
	Unit:	F
	Temperature Location:	ORAL CAVITY

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Nov/12/2020

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Unplanned Assessment Of Local Reaction**

1.	Date of Assessment:	Not Applicable _____ //	<a href="#">Comments</a>
2.	Injection Site Location	Not Applicable _____	<a href="#">Comments</a>
3.	Injection Site Body Side:	Not Applicable _____	<a href="#">Comments</a>

**Reaction**

4.a	Reaction:	REDNESS	
	Reaction Present:	Not Applicable _____	<a href="#">Comments</a>
4.b	Reaction:	SWELLING	
	Reaction Present:	Not Applicable _____	<a href="#">Comments</a>

**Symptom**

5.a	Symptom:	PAIN AT INJECTION SITE	
	Symptom Present:	Not Applicable _____	<a href="#">Comments</a>
5.b	Symptom:	FATIGUE/TIREDNESS	
	Symptom Present:	Not Applicable _____	<a href="#">Comments</a>
5.c	Symptom:	HEADACHE	
	Symptom Present:	Not Applicable _____	<a href="#">Comments</a>

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)



**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Nov/12/2020

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

5.d	Symptom:	VOMITING	
	Symptom Present:	Not Applicable _____	<a href="#">Comments</a>
5.e	Symptom:	DIARRHEA	
	Symptom Present:	Not Applicable _____	<a href="#">Comments</a>
5.f	Symptom:	NEW OR WORSENERED MUSCLE PAIN	
	Symptom Present:	Not Applicable _____	<a href="#">Comments</a>
5.g	Symptom:	NEW OR WORSENERED JOINT PAIN	
	Symptom Present:	Not Applicable _____	<a href="#">Comments</a>
5.h	Symptom:	CHILLS	
	Symptom Present:	Not Applicable _____	<a href="#">Comments</a>

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Nov/4/2020
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:** 1048

**Subject No:** 10481104

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

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1048) The Pain Center of Arizona

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

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

**Form Status:** Not Started

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

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

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

**Form Status:** Not Started

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**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	[ ]
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090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**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	FATIGUE	Sep/11/2020 07:00	NO End Date Time: Sep/12/2020 07:00	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	decreased hearing right ear	Nov/30/2020 UNK:UNK	NO End Date Time: Jan/21/2021 UNK:UNK	<a href="#">Repeating Pages</a>

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[FATIGUE]
4.	Start Date Time:	Sep/11/2020 07:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/12/2020 07:00
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:	RELATED

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	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	[ ]



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Answered Queries

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[decreased hearing right ear]
4.	Start Date Time:	Nov/30/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/21/2021 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Answered Queries

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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: [covid-19]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	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	[ ]

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**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**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:** 1048

**Subject No:** 10481104

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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**Medication Error**

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

**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**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:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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**Concomitant Medications**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**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>

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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**Concomitant Medications**

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

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**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**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:** 1048

**Subject No:** 10481104

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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**Radiation Treatment**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**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:** 1048

**Subject No:** 10481104

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

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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

**Header Text:** c4591001

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

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

**Site No:** 1048    **Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104    **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:** 1048    **Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104    **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:** 1048    **Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104    **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:	

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled    **Form:** VACCINATION

**Form Version:** 10-Dec-2020 02:26    **Form Status:** Not Started

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**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?	



**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:** 1048    **Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104    **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:** 1048    **Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104    **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:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** DATE OF VISIT

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**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	Dec/18/2020
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, Verified

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**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 per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	---

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** DATE OF VISIT

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Dec/30/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:31

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** INFORMED CONSENT - FURTHER VACCINATION

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Informed Consent - Further Vaccination**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Dec/30/2020
----	--------------	--

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

**Form Version:** 10-Dec-2020 02:30

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

**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
----	--	----------------

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION

**Form Version:** 10-Dec-2020 02:31

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

1.	Date of Completion/Discontinuation /Death :	Dec/30/2020
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]



**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Lab Urinalysis**

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

**Lab Result**

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

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**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	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/30/2020
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	[BPVSM5]
5.b	Sample ID	[BS69HJ]
5.c	Sample ID	[BS69HK]

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1048

**Subject No:** 10481104

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

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

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

**Site Name:** (1048) The Pain Center of Arizona

**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: Dec/30/2020
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	[BRJ863]
-----	-----------	----------

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** VACCINATION

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

**Site Name:** (1048) The Pain Center of Arizona

**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	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Dec/30/2020 12:15
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Dec/24/2020
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:** 1048

**Subject No:** 10481104

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

**Form:** WITHDRAWAL OF CONSENT

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Withdrawal Of Consent**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

**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 _____ [ ]

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** DATE OF VISIT

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Jan/20/2021
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

[Form Comments](#)

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**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>

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1048

**Subject No:** 10481104

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

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

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

**Site Name:** (1048) The Pain Center of Arizona

**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: Jan/20/2021
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	[BRJ86T]
-----	-----------	----------

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** VACCINATION

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

**Site Name:** (1048) The Pain Center of Arizona

**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	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/20/2021 10:06
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Verified

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Mar/8/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** CONTACT OUTCOME

**Form Status:** Data Complete, Verified

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Mar/8/2021
3.	Comments:	[ ]

**Header Text:** c4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V105\_MONTH18

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** V105\_MONTH18

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** FURTHER\_VACCINATION\_EOT -  
Unscheduled

**Form:** DISPOSITION - TREATMENT

**Form Version:** 20-Feb-2021 02:26

**Form Status:** Data Complete, Verified

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Mar/8/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1048) The Pain Center of Arizona

**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	Nov/4/2020

**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:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**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:** 1048

**Subject No:** 10481104

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

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

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Sep-11-2020 15:00:33 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Subject is not a screen fail <hr/> Not Applicable

**Header Text:** c4591001

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

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1048

**Subject No:** 10481104

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

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

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Item	Date	User	Comment
3	Sep-11-2020 17:57:39 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Documented hysterectomy, 2011
			Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1048

**Subject No:** 10481104

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

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

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Sep-30-2020 17:46:42 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1048

**Subject No:** 10481104

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

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

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Item	Date	User	Comment
1	Sep-30-2020 17:46:42 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1048

**Subject No:** 10481104

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

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

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Item	Date	User	Comment
2	Sep-30-2020 17:46:42 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1048

**Subject No:** 10481104

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

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

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Item	Date	User	Comment
3	Sep-30-2020 17:46:42 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1048

**Subject No:** 10481104

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

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

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Item	Date	User	Comment
4	Sep-30-2020 17:46:42 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1048

**Subject No:** 10481104

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

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

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Item	Date	User	Comment
5	Sep-30-2020 17:46:42 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1048

**Subject No:** 10481104

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

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

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Item	Date	User	Comment
6.a	Sep-30-2020 17:46:42 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1048

**Subject No:** 10481104

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

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

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Item	Date	User	Comment
6.a	Sep-30-2020 17:46:42 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1048

**Subject No:** 10481104

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

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

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Item	Date	User	Comment
6.a	Sep-30-2020 17:46:42 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** Unplanned 1

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** CONTACT OUTCOME - UNPLANNED - Comments

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Item	Date	User	Comment
3	Nov-20-2020 10:31:30 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Nov/12/2020

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - Comments

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
Form	Nov-30-2020 10:58:13 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

**Header Text:** c4591001

**Visit:** Unplanned 1

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -  
SYSTEMIC EVENT - Comments

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Item	Date	User	Comment
1	Nov-30-2020 10:58:13 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable
1	Nov-16-2020 13:29:58 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

**Header Text:** c4591001

**Visit:** Unplanned 1

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -  
SYSTEMIC EVENT - Comments

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
2	Nov-30-2020 10:58:13 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Unplanned 1

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - Comments

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Item	Date	User	Comment
3	Nov-30-2020 10:58:13 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable
3	Nov-20-2020 10:32:45 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

**Header Text:** c4591001

**Visit:** Unplanned 1

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -  
SYSTEMIC EVENT - Comments

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
4.a	Nov-30-2020 10:58:13 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Unplanned 1

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -  
SYSTEMIC EVENT - Comments

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
4.b	Nov-30-2020 10:58:13 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Unplanned 1

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - Comments

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
5.a	Nov-30-2020 10:58:13 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** Unplanned 1

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -  
SYSTEMIC EVENT - Comments

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Item	Date	User	Comment
5.b	Nov-30-2020 10:58:13 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

**Header Text:** c4591001

**Visit:** Unplanned 1

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -  
SYSTEMIC EVENT - Comments

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
5.c	Nov-30-2020 10:58:13 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Unplanned 1

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -  
SYSTEMIC EVENT - Comments

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Item	Date	User	Comment
5.d	Nov-30-2020 10:58:13 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

**Header Text:** c4591001

**Visit:** Unplanned 1

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -  
SYSTEMIC EVENT - Comments

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
5.e	Nov-30-2020 10:58:13 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Unplanned 1

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -  
SYSTEMIC EVENT - Comments

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
5.f	Nov-30-2020 10:58:13 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Unplanned 1

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - Comments

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
5.g	Nov-30-2020 10:58:13 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Unplanned 1

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION -  
SYSTEMIC EVENT - Comments

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Item	Date	User	Comment
5.h	Nov-30-2020 10:58:13 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Form Version:** 10-Dec-2020 02:30

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
Form	Jan-07-2021 11:53:38 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable



**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1048

**Subject No:** 10481104

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

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

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Item	Date	User	Comment
3	Jan-07-2021 12:01:42 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1048

**Subject No:** 10481104

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

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

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Item	Date	User	Comment
6.a	Jan-07-2021 11:59:16 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Documented hysterectomy
			Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1048

**Subject No:** 10481104

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

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

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Item	Date	User	Comment
6.a	Jan-07-2021 11:59:16 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Documented hysterectomy
			Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1048

**Subject No:** 10481104

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

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

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Item	Date	User	Comment
6.a	Jan-07-2021 11:59:16 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Documented hysterectomy
			Not Applicable

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** WITHDRAWAL OF CONSENT - Comments

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Jan-13-2021 09:01:52 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Disposition

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** WITHDRAWAL OF CONSENT - Comments

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Item	Date	User	Comment
1	Jan-13-2021 09:01:52 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** DEATH DETAILS CODED - Comments

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Jan-13-2021 09:02:26 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Disposition

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** DEATH DETAILS CODED - Comments

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Item	Date	User	Comment
1	Jan-13-2021 09:02:26 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1048

**Subject No:** 10481104

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

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

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Jan-20-2021 11:29:54 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1048

**Subject No:** 10481104

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

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

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Item	Date	User	Comment
1	Jan-20-2021 11:29:54 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1048

**Subject No:** 10481104

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

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

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Item	Date	User	Comment
2	Jan-20-2021 11:29:54 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1048

**Subject No:** 10481104

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

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

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Item	Date	User	Comment
3	Jan-20-2021 11:29:54 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1048

**Subject No:** 10481104

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

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

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Item	Date	User	Comment
4	Jan-20-2021 11:29:54 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1048

**Subject No:** 10481104

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

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

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Item	Date	User	Comment
5	Jan-20-2021 11:29:54 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1048

**Subject No:** 10481104

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

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

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Item	Date	User	Comment
6.a	Jan-20-2021 11:29:54 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1048

**Subject No:** 10481104

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

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

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Item	Date	User	Comment
6.a	Jan-20-2021 11:29:54 (UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 10-Dec-2020 02:23

**Site No:** 1048

**Subject No:** 10481104

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

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

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Item	Date	User	Comment
6.a	Jan-20-2021 11:29:54 (UTC-07:00) Mountain 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:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Jan-28-2021 12:41:40 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated

**Affidavit:**

N/A

Abram Burgher	Approved	Jan-20-2021 15:59:20 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, AbramBurgher, 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	Dec-16-2020 14:10:01 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Abram Burgher	Approved	Dec-11-2020 11:28:15 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

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

**Form Status:** Data Complete, Verified

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

**Affidavit:**

By my dated signature below, I, AbramBurgher, 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	Dec-08-2020 09:52:06 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Abram Burgher	Approved	Dec-03-2020 08:27:22 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, AbramBurgher, 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	Dec-03-2020 07:48:28 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Abram Burgher	Approved	Dec-02-2020 15:42:16 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

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

**Form Status:** Data Complete, Verified

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

**Affidavit:**

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

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

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

(b) (6)	N/A	Nov-20-2020 10:31:30 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Abram Burgher	Approved	Nov-18-2020 08:13:56 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Nov-17-2020 16:02:05 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Abram Burgher	Approved	Nov-16-2020 17:40:02 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

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

**Form Status:** Data Complete, Verified

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

**Affidavit:**

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

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

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

(b) (6)	N/A	Nov-16-2020 13:26:31 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Abram Burgher	Approved	Nov-06-2020 09:51:15 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, AbramBurgher, 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.

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION - eCRF Audit Trail History

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Sep-11-2020 14:51:07 (UTC-07:00) Mountain 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
Sep-11-2020 14:51:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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*I. Consent Was:*

Date	Location	User	Value	Reason
Sep-19-2020 12:52:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtai ned  Sep/9/2020	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481104

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Subject ID**

Date	Location	User	Value	Reason
Sep-11-2020 14:24:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10481104	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Sep-11-2020 14:24:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1963	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Sep-11-2020 14:48:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Sep-11-2020 14:48:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LATIN O(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 14:48:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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**I. Date of Visit**

Date	Location	User	Value	Reason
Sep-11-2020 14:54:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-11-2020 14:54:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/9/2020	Transcription Error
Sep-11-2020 14:53:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of Visit, 09/Nov/2020 is a future date relative to when it was entered on 11/Sep /2020. Please correct.
Sep-11-2020 14:53:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/9/2020	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Sep-11-2020 15:12:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/9/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Sep-11-2020 15:12:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Sep-11-2020 15:12:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1048

Subject No: 10481104

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

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

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*I.a*

Date	Location	User	Value	Reason
Sep-11-2020 15:16:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 1 <b>Medical History Term:</b> Immune mediated thyroiditis <b>Start Date:</b> UNK/UNK/2010 <b>Ongoing:</b> YES	Initial Entry

*I.a Line/MH Number:*

Date	Location	User	Value	Reason
Sep-11-2020 15:16:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 15:16:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Immune mediated thyroiditis	Initial Entry

*I.a Start Date:*

Date	Location	User	Value	Reason
Sep-11-2020 15:16:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2010	Initial Entry

*I.a Ongoing:*

Date	Location	User	Value	Reason
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090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

Sep-11-2020 15:16:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry
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*1.b*

Date	Location	User	Value	Reason
Sep-13-2020 08:15:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Line/MH Num</b> 2 <b>ber:</b> <b>Medical Histor</b> Migraine <b>y Term:</b> <b>Start Date:</b> UNK/UNK /1995 <b>Ongoing:</b> YES	Transcription Error
Sep-11-2020 15:26:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Num</b> 2 <b>ber:</b> <b>Medical Histor</b> Migrane <b>y Term:</b> <b>Start Date:</b> UNK/UNK /1995 <b>Ongoing:</b> YES	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1048

Subject No: 10481104

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

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

**I.b Line/MH Number:**

Date	Location	User	Value	Reason
Sep-11-2020 15:26:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**I.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Sep-13-2020 09:23:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Sep-13-2020 08:15:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-13-2020 08:15:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Migraine	Transcription Error
Sep-12-2020 11:53:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify MIGRANE as follows...Should the spelling be MIGRAINE? If so, edit. Otherwise clarify. Thank you.
Sep-11-2020 15:26:19 (UTC-07:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Migraine	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1048

Subject No: 10481104

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

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

Mountain Time (US & Canada)

***1.b Start Date:***

Date	Location	User	Value	Reason
Sep-11-2020 15:26:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1995	Initial Entry

***1.b Ongoing:***

Date	Location	User	Value	Reason
Sep-11-2020 15:26:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.c***

Date	Location	User	Value	Reason
Sep-11-2020 15:27:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 3 <b>Medical History Term:</b> Hysterectomy <b>Start Date:</b> UNK/UNK/2011 <b>Ongoing:</b> NO End Date: UNK/UNK/2011	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1048

Subject No: 10481104

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

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

**I.c Line/MH Number:**

Date	Location	User	Value	Reason
Sep-11-2020 15:27:51 (UTC-07:00) Mountain 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
Sep-11-2020 15:27:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hysterectomy	Initial Entry

**I.c Start Date:**

Date	Location	User	Value	Reason
Sep-11-2020 15:27:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2011	Initial Entry

**I.c Ongoing:**

Date	Location	User	Value	Reason
Sep-11-2020 15:27:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2011	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1048

Subject No: 10481104

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

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

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**1. Date:**

Date	Location	User	Value	Reason
Sep-11-2020 17:49:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/9/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Sep-11-2020 17:49:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 143.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Sep-11-2020 17:49:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Sep-11-2020 17:49:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 65.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Sep-11-2020 17:49:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> in	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
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090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1048

Subject No: 10481104

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

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

Sep-11-2020 17:49:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 23.8	Initial Entry
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7.a

Date	Location	User	Value	Reason
Sep-11-2020 17:49:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Record Identifi 1 er:: Temperature: 97.4 Temperature U F nit: Temperature L ORAL CA ocation:: VITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-11-2020 17:49:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-11-2020 17:49:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 97.4	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-11-2020 17:49:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

Sep-11-2020 17:49:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry
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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481104

Subject Initials: ---

Generated By: (b) (4)

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

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3. Collection Date:

Date	Location	User	Value	Reason
Sep-11-2020 17:57:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-11-2020 17:52:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> 113 : <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> <b>Not Done::</b> NOT DONE	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-11-2020 17:52:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-11-2020 17:52:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
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090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

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

**Form Version:** 21-Aug-2020 02:49

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

Sep-11-2020 17:52:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry
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**Header Text:** c4591001

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

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** RANDOMIZATION - eCRF Audit Trail History

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Sep-11-2020 18:00:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/9/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Sep-11-2020 18:00:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 255038	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (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: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481104

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-19-2020 12:52:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-19-2020 12:52:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-19-2020 12:52:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-19-2020 12:52:46 (UTC-07:00) Mountain 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-19-2020 12:52:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/9/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (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: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481104

Subject Initials: ---

Generated By: (b) (4)

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

Sep-19-2020 12:52:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP3LNK	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Sep-19-2020 12:52:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP3LNK	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-19-2020 12:53:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP3LNL	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-19-2020 12:53:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP3LNL	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-19-2020 12:53:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP3LNM	Initial Entry

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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: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481104

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sample ID

Date	Location	User	Value	Reason
Sep-19-2020 12:53:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP3LNM	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-19-2020 12:53:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPL2M3	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Sep-19-2020 12:53:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPL2M3	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-19-2020 12:53:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPL2M4	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Sep-19-2020 12:53:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPL2M4	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (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: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481104

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-19-2020 10:37:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-19-2020 10:37:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-19-2020 10:37:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-19-2020 10:37:37 (UTC-07:00) Mountain 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-19-2020 10:37:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/9/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (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:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

Sep-19-2020 10:37:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP3LRH	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-19-2020 10:37:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP3LRH	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1048

Subject No: 10481104

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

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

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-11-2020 18:11:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-11-2020 18:11:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-11-2020 18:11:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-11-2020 18:11:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/9/2020 15:49	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-11-2020 18:11:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
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090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** VACCINATION - eCRF Audit Trail History

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

Sep-11-2020 18:11:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry
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**7. Route:**

Date	Location	User	Value	Reason
Sep-11-2020 18:11:44 (UTC-07:00) Mountain 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-11-2020 18:11:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 18:11:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Sep-19-2020 10:37:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICITY E -DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-30-2020 17:46:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/30/2020	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 15-Sep-2020 21:54

Site No: 1048

Subject No: 10481104

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

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

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**1. Date:**

Date	Location	User	Value	Reason
Sep-30-2020 17:46:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/30/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-30-2020 17:46:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> <b>Temperature: 97.9</b> <b>Temperature Unit:</b> <b>Temperature Location:</b> ORAL CAVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-30-2020 17:46:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-30-2020 17:46:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 97.9	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
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090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

Sep-30-2020 17:46:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry
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**2.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-30-2020 17:46:29 (UTC-07:00) Mountain 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: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481104

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-30-2020 17:46:42 (UTC-07:00) Mountain 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-30-2020 17:46:42 (UTC-07:00) Mountain 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-30-2020 17:46:42 (UTC-07:00) Mountain 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-30-2020 17:46:42 (UTC-07:00) Mountain 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-30-2020 17:46:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a**

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481104

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-30-2020 17:46:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-30-2020 17:46:42 (UTC-07:00) Mountain 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-30-2020 17:46:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-30-2020 17:46:42 (UTC-07:00) Mountain 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-30-2020 17:46:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (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: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481104

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-01-2020 09:37:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-01-2020 09:37:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-01-2020 09:37:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-01-2020 09:37:08 (UTC-07:00) Mountain 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-01-2020 09:37:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/30/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (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:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

Oct-01-2020 09:37:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP3LWK	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-01-2020 09:37:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP3LWK	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1048

Subject No: 10481104

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

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

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-30-2020 17:47:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-30-2020 17:47:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-30-2020 17:47:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-30-2020 17:47:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/30/2020 13:31	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-30-2020 17:47:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
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090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1048

Subject No: 10481104

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

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

Sep-30-2020 17:47:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry
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**7. Route:**

Date	Location	User	Value	Reason
Sep-30-2020 17:47:18 (UTC-07:00) Mountain 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-30-2020 17:47:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 17:47:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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**I. Date of Visit**

Date	Location	User	Value	Reason
Nov-16-2020 16:34:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-16-2020 14:17:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	ILLNESS VISIT ENTERED
Nov-16-2020 09:50:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Illness eDiary: As per Illness ediary records, subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 12NOV2020. But there is no COVID Illness visit reported in the database.
Nov-04-2020 09:51:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/4/2020	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Nov-04-2020 17:03:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-04-2020 17:03:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-04-2020 17:03:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-04-2020 17:03:28 (UTC-07:00) Mountain 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-04-2020 17:03:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/4/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)



Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481104

Subject Initials: ---

Generated By: (b) (4)

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

Nov-04-2020 17:03:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BPVSLD</b>	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Nov-04-2020 17:03:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPVSLD	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-04-2020 17:03:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BS69G3</b>	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-04-2020 17:03:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BS69G3	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-04-2020 17:03:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BS69G2</b>	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-04-2020 17:03:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BS69G2	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**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:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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**I. Date of Visit**

Date	Location	User	Value	Reason
Nov-30-2020 14:20:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Nov-30-2020 14:20:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Nov-30-2020 10:31:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	updated
Nov-30-2020 10:31:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	updated
Nov-22-2020 23:29:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Reissued:Opened	DM1: Data is not updated as per query. Kindly review and provide missing information on 'ILL POTEN' form under this visit. Else clarify.
Nov-22-2020 23:28:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	DM1: Data is not updated as per query. Kindly review and provide missing information on 'COVID TEST' form under this

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**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:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

				visit. Else clarify.
Nov-20-2020 10:37:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Original value is correct
Nov-20-2020 10:36:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Original value is correct
Nov-18-2020 02:31:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	DM: Kindly review and complete 'Illness Details form' at this visit. Thank you.
Nov-18-2020 02:31:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM: Kindly review and complete 'Microbiology Specimen form' at this visit. Thank you.
Nov-16-2020 13:36:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-16-2020 13:33:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Nov-16-2020 13:31:53 (UTC-07:00) Mountain 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

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**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1048  
**Subject No:** 10481104  
**Generated By:** (b) (4)

**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History  
**Form Status:** Data Complete, Frozen, Verified  
**Site Name:** (1048) The Pain Center of Arizona  
**Subject Initials:** ---  
**Generated Time (GMT):** 19-Apr-2021 21:04

				as appropriate.
Nov-16-2020 13:31:53 (UTC-07:00) Mountain 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-16-2020 13:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/12/2020	Initial Entry

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

Date	Location	User	Value	Reason
Nov-16-2020 13:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 -  
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**Form Version:** 10-Oct-2020 16:02

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Nov-16-2020 13:33:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/12/2020	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Nov-16-2020 13:33:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/11/2020	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Feb-22-2021 07:25:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-19-2021 16:21:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-19-2021 16:21:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Symptom Re solved:  Dec/16/2020	New Information
Feb-02-2021 06:43:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Please clarify whether the reported symptoms are still ongoing?

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**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020  
**Form Version:** 10-Oct-2020 16:02  
**Site No:** 1048  
**Subject No:** 10481104  
**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:** (1048) The Pain Center of Arizona  
**Subject Initials:** ---  
**Generated Time (GMT):** 19-Apr-2021 21:04

				If symptoms have ended, please update 'Symptoms Ongoing' on to 'NO' and add Date of Last Symptom Resolved on the CRF.
Feb-01-2021 14:41:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	CLINQUERY: Please clarify whether the reported symptoms are still ongoing? If symptoms have ended, please update 'Symptoms Ongoing' on to 'NO' and add Date of Last Symptom Resolved on the CRF.
Nov-16-2020 13:33:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.a**

Date	Location	User	Value	Reason
Nov-16-2020 13:33:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b> YES	Initial Entry

**4.a Symptoms:**

Date	Location	User	Value	Reason
Nov-16-2020 13:33:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020**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:** 1048**Site Name:** (1048) The Pain Center of Arizona**Subject No:** 10481104**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 19-Apr-2021 21:04**4.a Was symptom present?**

Date	Location	User	Value	Reason
Nov-16-2020 13:33:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.b**

Date	Location	User	Value	Reason
Nov-16-2020 13:33:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom</b> NEW OR INCR <b>s:</b> EASED COUGH <b>Symptom</b> NO <b>Present:</b>	Initial Entry

**4.b Symptoms:**

Date	Location	User	Value	Reason
Nov-16-2020 13:33:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED CO UGH	Initial Entry

**4.b Was symptom present?**

Date	Location	User	Value	Reason
Nov-16-2020 13:33:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.c**

Date	Location	User	Value	Reason
Nov-16-2020 13:33:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sympto</b> NEW OR INCREA <b>ms:</b> SED SHORTNESS OF BREATH	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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Form Status: Data Complete, Frozen, Not Complete

Site No: 1048

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Subject No: 10481104

Subject Initials: ---

Generated By: (b) (4)

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			Symptom Present:	
--	--	--	------------------	--

4.c Symptoms:

Date	Location	User	Value	Reason
Nov-16-2020 13:33:41 (UTC-07:00) Mountain 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-16-2020 13:33:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Nov-16-2020 13:33:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms: CHILLS Symptom Present: YES	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Nov-16-2020 13:33:41 (UTC-07:00) Mountain 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-16-2020 13:33:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

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**Subject Initials:** ---

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

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**4.e**

Date	Location	User	Value	Reason
Nov-16-2020 13:33:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED MUSCLE PAIN <b>Symptom Present:</b> YES	Initial Entry

**4.e Symptoms:**

Date	Location	User	Value	Reason
Nov-16-2020 13:33:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED MUSCLE PAIN	Initial Entry

**4.e Was symptom present?**

Date	Location	User	Value	Reason
Nov-16-2020 13:33:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.f**

Date	Location	User	Value	Reason
Nov-16-2020 13:33:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW LOSS OF TASTE OR SMELL <b>Symptom Present:</b> NO	Initial Entry

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Header Text: c4591001

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Site No: 1048

Site Name: (1048) The Pain Center of Arizona

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Generated By: (b) (4)

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4.f Symptoms:

Date	Location	User	Value	Reason
Nov-16-2020 13:33:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Nov-16-2020 13:33:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Nov-16-2020 13:33:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom:</b> NEW OR INCRE ASED SORE TH ROAT <b>Symptom Present:</b> NO	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Nov-16-2020 13:33:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SOR E THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Nov-16-2020 13:33:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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**Header Text:** c4591001

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**Site No:** 1048

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

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**4.h**

Date	Location	User	Value	Reason
Nov-16-2020 13:33:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> DIARRHE A <b>Symptom Present:</b> NO	Initial Entry

**4.h Symptoms:**

Date	Location	User	Value	Reason
Nov-16-2020 13:33:41 (UTC-07:00) Mountain 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-16-2020 13:33:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.i**

Date	Location	User	Value	Reason
Nov-16-2020 13:33:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITIN G <b>Symptom Present:</b> NO	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
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**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

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**Subject Initials:** ---

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

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**4.i Symptoms:**

Date	Location	User	Value	Reason
Nov-16-2020 13:33:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

**4.i Was symptom present?**

Date	Location	User	Value	Reason
Nov-16-2020 13:33:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**Form:** MICROBIOLOGY SPECIMEN - Audit Trail

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

**Form Status:**

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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Date	Location	User	Value	Reason
Nov-30-2020 10:27:32 (UTC-07:00) Mountain Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Not Complete

Site No: 1048

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Subject Initials: ---

Generated By: (b) (4)

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**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Nov-30-2020 10:43:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/12/2020	Transcription Error
Nov-30-2020 10:27:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/13/2020	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Nov-30-2020 10:27:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWABBED MATERIAL	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Nov-30-2020 10:27:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NASOPHARYNX	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Nov-30-2020 10:27:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	<b>Data Entry:</b> SEVERE ACUTE RESP SYND ROME CORONAVIRUS 2	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Nov-30-2020 10:27:32	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
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**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

(UTC-07:00) Mountain  
Time (US & Canada)

(autocalc)

SARS-COV-2 DIAGNOSTIC T  
EST

**6. Trade Name:**

Date	Location	User	Value	Reason
Dec-02-2020 12:47:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Initial Entry
Dec-02-2020 12:47:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry
Dec-01-2020 23:18:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	DM: Per query response provided, Please update data when available. Thank you
Dec-01-2020 16:56:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	UNKNOWN - PENDING MEDICAL RECORDS
Nov-30-2020 23:14:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Trade Name and Results" is missing. Kindly review and update.

**7. Test Result:**

Date	Location	User	Value	Reason
Dec-02-2020 12:47:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> POSITIVE	Initial Entry
Nov-30-2020 10:44:41 (UTC-07:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
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**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

Mountain Time (US & Canada)		(b) (4), (b) (6)		
Nov-30-2020 10:27:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> POSITIVE	Initial Entry

**9. Trade Name Other, Specify:**

Date	Location	User	Value	Reason
Jan-06-2021 03:56:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Data updated is acceptable. Spelling error is corrected.
Dec-18-2020 00:12:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Candidate	Added to Q and A tracker
Dec-16-2020 14:06:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	the text 'CLIA-certified lab' will not fit in this particular field.
Dec-11-2020 06:34:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM : Please include the text 'CLIA-certified lab' in the response to this particular field
Dec-08-2020 09:52:06 (UTC-07:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answer	adding additional info: the test

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
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**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

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**Subject Initials:** ---

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

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

Mountain Time (US & Canada)			d	was performed at a CLIA-certified lab
Dec-08-2020 09:52:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : BD Veritor SARS-CoV-2 Rapid Detection Kit - CLIA-c	adding additional info: the test was performed at a CLIA-certified lab
Dec-04-2020 00:02:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: Please indicate whether the test was conducted in a CLIA-certified laboratory or by a laboratory accredited by the ISO 15189 by including the text "CLIA-certified lab" or "ISO 15189" in the response to this particular field.
Dec-03-2020 07:48:28	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An	Changed Information

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

(UTC-07:00) Mountain Time (US & Canada)			swere d	
Dec-03-2020 07:48:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : BD V eritor SARS -CoV- 2 Rap id Det ection Kit	Changed Information
Dec-03-2020 02:49:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Op ened	bd varitor system is not indicated on the FDA cleared (including Emergency Use Authorization) diagnostic list and is not indicated as CLIA certified lab or ISO 15189 accredited lab . Please verify and update as appropriate. Otherwise, please provide clarification. (b) (4)
Dec-02-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data</b>	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

12:47:16 (UTC-07:00) Mountain Time (US & Canada)		(b) (4), (b) (6)	<b>Entry</b> : BD V aritor Syste m	
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

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

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Nov-16-2020 13:36:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-16-2020 13:36:21 (UTC-07:00) Mountain 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-17-2020 16:03:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Nov-17-2020 16:02:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	There are more than 1 barcode present for sample collection. Please review and correct as appropriate.
Nov-16-2020 13:36:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-16-2020 13:36:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

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

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

				review and correct as appropriate.
Nov-16-2020 13:36:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/13/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-17-2020 16:03:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b>	RR03268 is the correct bar code for the home collection swab.
Nov-16-2020 13:36:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRJ85N	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Nov-17-2020 16:03:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	RR03268 is the correct bar code for the home collection swab.
Nov-16-2020 18:00:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-16-2020 15:21:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	ECRF UPDATED
Nov-16-2020 14:31:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Please clarify Sample ID for NASAL

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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
SELF - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1048**Site Name:** (1048) The Pain Center of Arizona**Subject No:** 10481104**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 19-Apr-2021 21:04

Canada)				SWAB SELF CRF. SWAB PFE is also blank. Please refer to CRF CR sections 8.16 and 8.32 for instructions. Please review and update as appropriate. Thank you.
Nov-16-2020 13:38:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	BRJ85N is confirmed as entered
Nov-16-2020 13:36:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Barcode is not 7 characters in length. Please review and correct as appropriate.
Nov-16-2020 13:36:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRJ85N	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Nov-17-2020 16:02:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> RR03268	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Nov-17-2020 16:02:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RR03268	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**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:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Nov-16-2020 15:20:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-16-2020 15:20:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-16-2020 15:20:55 (UTC-07:00) Mountain 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-16-2020 15:20:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HOME SWAB COLLECTE D AND SHIPPED	Initial Entry

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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1048**Site Name:** (1048) The Pain Center of Arizona**Subject No:** 10481104**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 19-Apr-2021 21:04[Back to Form](#)**I.a**

Date	Location	User	Value	Reason
Nov-16-2020 13:41:03 (UTC-07:00) Mountain 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
Nov-16-2020 13:40:47 (UTC-07:00) Mountain 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>	Initial Entry

**I.a Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Nov-16-2020 13:40:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SPECIALIST	Initial Entry

**I.a Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Nov-16-2020 13:41:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**I.b**

Date	Location	User	Value	Reason
Nov-16-2020 13:41:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENCY ROOM	Initial Entry



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481104

Subject Initials: ---

Generated By: (b) (4)

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

			Occurrence of NO Visits or Conta cts:	
Nov-16-2020 13:40:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practiti</b> EMERGE <b>oner:</b> NCY ROO M <b>Occurrence of</b> <b>Visits or Conta</b> <b>cts:</b>	Initial Entry

***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-16-2020 13:40:47 (UTC-07:00) Mountain 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-16-2020 13:41:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.c***

Date	Location	User	Value	Reason
Nov-16-2020 13:41:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Pract</b> PRIMARY C <b>itioner:</b> ARE PHYSI CIAN <b>Occurrence o</b> NO <b>f Visits or Co</b> <b>ntacts:</b>	Initial Entry
Nov-16-2020 13:40:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Pract</b> PRIMARY C <b>itioner:</b> ARE PHYSI	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:59

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

			CIAN	
			<b>Occurrence of Visits or Contacts:</b>	

***1.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-16-2020 13:40:47 (UTC-07:00) Mountain 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-16-2020 13:41:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.d***

Date	Location	User	Value	Reason
Nov-16-2020 13:40:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> URGENT CARE <b>Occurrence of Visits or Contacts:</b> YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
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**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:59

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

***I.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-16-2020 13:40:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> URGENT CARE	Initial Entry

***I.d Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-16-2020 13:40:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Number of Visits or Contact s:</i>  1	Initial Entry

***I.e***

Date	Location	User	Value	Reason
Nov-16-2020 13:41:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHON E CONSULT ATION  <b>Occurrence of f Visits or Co ntacts:</b> NO	Initial Entry
Nov-16-2020 13:40:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHON E CONSULT ATION  <b>Occurrence of f Visits or Co ntacts:</b>	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:59

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**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-16-2020 13:40:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> TELEPHONE CONSULTATI ON	Initial Entry

***1.e Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-16-2020 13:41:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.f***

Date	Location	User	Value	Reason
Nov-16-2020 13:41:03 (UTC-07:00) Mountain 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
Nov-16-2020 13:40:47 (UTC-07:00) Mountain 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>	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

*1.f Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Nov-16-2020 13:40:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> OTHER	Initial Entry

*1.f Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Nov-16-2020 13:41:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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

Date	Location	User	Value	Reason
Nov-16-2020 13:40:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020

**Form:** ILLNESS DETAILS - eCRF Audit Trail History

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Nov-30-2020 10:29:38 (UTC-07:00) Mountain 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
Dec-02-2020 10:36:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-02-2020 07:51:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Dec-02-2020 07:51:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnosis:</i>  COVID - 19  Date of Diagnosis:  Nov/12/2020	Transcription Error
Dec-02-2020 07:18:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY: Since local SARS-CoV-2-NAAT test was positive on 12Nov2020, please consider updating the date of the COVID-19

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled  
Visit on Nov/12/2020**Form:** ILLNESS DETAILS - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:52**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1048**Site Name:** (1048) The Pain Center of Arizona**Subject No:** 10481104**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 19-Apr-2021 21:04

				diagnosis as 12Nov2020.
Dec-01-2020 21:29:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-01-2020 16:58:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query
Dec-01-2020 16:58:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagn osis:</i>  COVID - 19  Date of Diagnosis:  Nov/13/2020	New Information
Nov-30-2020 14:21:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Yes is selected, however, the diagnosis details is missing. Please correct.
Nov-30-2020 10:30:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	updated
Nov-30-2020 10:29:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Yes is selected, however, either the diagnosis details or date of diagnosis is missing. Please correct.
Nov-30-2020 10:29:38 (UTC-07:00) Mountain Time (US &	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Diagnosis:	Initial Entry

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled      **Form:** ILLNESS DETAILS - eCRF Audit Trail History  
 Visit on Nov/12/2020  
**Form Version:** 06-Jul-2020 21:52      **Form Status:** Data Complete, Frozen, Not Complete  
**Site No:** 1048      **Site Name:** (1048) The Pain Center of Arizona  
**Subject No:** 10481104      **Subject Initials:** ---  
**Generated By:** (b) (4)      **Generated Time (GMT):** 19-Apr-2021 21:04

Canada)			Nov/13/2020	
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**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Nov-30-2020 10:59:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Transcription Error
Nov-30-2020 10:29:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry



**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF  
Audit Trail History

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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**1. Date of Visit**

Date	Location	User	Value	Reason
Dec-16-2020 14:10:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/16/2020	Initial Entry

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

Date	Location	User	Value	Reason
Dec-16-2020 14:10:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COVID_A1	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Dec/16/2020

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

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Dec-16-2020 14:12:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-16-2020 14:12:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-16-2020 14:12:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-16-2020 14:12:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-16-2020 14:12:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Dec/16/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Dec/16/2020

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

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

Dec-16-2020 14:12:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPVSLX	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Dec-16-2020 14:12:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPVSLX	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Dec-16-2020 14:13:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BS69H2	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Dec-16-2020 14:13:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BS69H2	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Dec-16-2020 14:13:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BS69H3	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Dec-16-2020 14:13:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BS69H3	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Nov/12/2020

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Nov-16-2020 13:26:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/12/2020	Initial Entry

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Nov/12/2020

**Form:** UNPLANNED VISIT - eCRF Audit Trail History

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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*I. Assessments*

Date	Location	User	Value	Reason
Nov-16-2020 13:27:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-16-2020 13:26:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate.
Nov-16-2020 13:26:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CONTACT OUTCOME	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Nov/12/2020

**Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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**1. Contact Type:**

Date	Location	User	Value	Reason
Nov-16-2020 13:27:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Nov-22-2020 21:18:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-20-2020 10:33:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Nov-17-2020 15:41:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Please add a form level "Not Applicable". Thank you.
Nov-17-2020 14:18:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject is not in the reactogenicity sub set. Not applicable
Nov-17-2020 00:15:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Contact Outcome' is selected as 'VISIT ARRANGED' but no 'UNPLANNED ASSESSMENT OF LOCAL REACTION' form is entered. Please review and update

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Nov/12/2020

**Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

				as appropriate.
Nov-16-2020 13:27:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Contact Outcome' is selected as 'VISIT ARRANGED' but no 'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' form(s) is/are entered. Please review and update as appropriate.
Nov-16-2020 13:27:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact:  Nov/12/2020  Contact Outcome:  VISIT ARRANGED	Initial Entry

**3. Comments:**

Date	Location	User	Value	Reason
Nov-20-2020 10:31:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Nov/12/2020

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:01

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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**1. Date:**

Date	Location	User	Value	Reason
Nov-16-2020 13:28:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/12/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Nov-16-2020 13:28:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 <b>Temperature:</b> 100.5 <b>Temperature Unit:</b> F <b>Temperature Location:</b> ORAL CAVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Nov-16-2020 13:28:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Nov-16-2020 16:05:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-16-2020 13:31:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	TEMPERTURE REPORTED BY SUBJECT WAS

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)



**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Nov/12/2020

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:01

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

Canada)				100.5 AS NOTED IN THE EDC
Nov-16-2020 13:28:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 100.5 F is outside of Normal Range 97 - 99.5 F.
Nov-16-2020 13:28:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 100.5	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Nov-16-2020 13:28:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Nov-16-2020 13:28:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Nov/12/2020

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Nov-30-2020 23:51:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-30-2020 10:58:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	updated
Nov-22-2020 23:10:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM : Please review and either update the data or entered form level comment as Not Applicable. Else, clarify.
Nov-20-2020 10:33:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Nov-17-2020 22:15:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly consider to update this form or else mark Not Applicable by selecting form level comment. Thank you.
Nov-16-2020 13:29:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Injection Site Location**

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Nov/12/2020

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481104

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-30-2020 10:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

3. Injection Site Body Side:

Date	Location	User	Value	Reason
Nov-20-2020 10:32:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

4.a

Date	Location	User	Value	Reason
Nov-30-2020 10:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Reaction::</b> REDNESS <b>Reaction Present:</b> Not Applicable	Initial Entry
Nov-16-2020 13:29:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Reaction::</b> REDNESS <b>Reaction Present:</b> S	Initial Entry

4.a Reaction:

Date	Location	User	Value	Reason
Nov-16-2020 13:29:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> REDNESS	Initial Entry

4.a Reaction Present:

Date	Location	User	Value	Reason
Nov-30-2020 10:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Nov/12/2020

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:57

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481104

Subject Initials: ---

Generated By: (b) (4)

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

4.b

Date	Location	User	Value	Reason
Nov-30-2020 10:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Reaction::</b> SWELLIN G <b>Reaction Present::</b> Not Applicable	Initial Entry
Nov-16-2020 13:29:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Reaction::</b> SWELLIN G <b>Reaction Present::</b>	Initial Entry

4.b Reaction:

Date	Location	User	Value	Reason
Nov-16-2020 13:29:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry

4.b Reaction Present:

Date	Location	User	Value	Reason
Nov-30-2020 10:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-30-2020 10:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> PAIN AT INJECTION SITE <b>Symptom Present::</b> Not Applicable	Initial Entry
Nov-16-2020 13:29:58	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Nov/12/2020

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

(UTC-07:00) Mountain Time (US & Canada)	(b) (4), (b) (6)	<b>Symptom::</b> PAIN AT INJECTION SITE <b>Symptom Present::</b>
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**5.a Symptom:**

Date	Location	User	Value	Reason
Nov-16-2020 13:29:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

**5.a Symptom Present:**

Date	Location	User	Value	Reason
Nov-30-2020 10:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Nov-30-2020 10:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FATIGUE/TIRE DNESS <b>Symptom P</b> Not Applicable <b>resent::</b>	Initial Entry
Nov-16-2020 13:29:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FATIGUE/TIRE DNESS <b>Symptom P</b> <b>resent::</b>	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Nov/12/2020

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

**5.b Symptom:**

Date	Location	User	Value	Reason
Nov-16-2020 13:29:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FATIGUE/TIREDNESS	Initial Entry

**5.b Symptom Present:**

Date	Location	User	Value	Reason
Nov-30-2020 10:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Nov-30-2020 10:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HEADACHE <b>Symptom Present::</b> Not Applicable	Initial Entry
Nov-16-2020 13:29:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HEADACHE <b>Symptom Present::</b>	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Nov/12/2020

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

**5.c Symptom:**

Date	Location	User	Value	Reason
Nov-16-2020 13:29:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HEADACHE	Initial Entry

**5.c Symptom Present:**

Date	Location	User	Value	Reason
Nov-30-2020 10:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Nov-30-2020 10:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VOMITIN G <b>Symptom Present::</b> Not Applicable	Initial Entry
Nov-16-2020 13:29:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VOMITIN G <b>Symptom Present::</b>	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Nov/12/2020

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

**5.d Symptom:**

Date	Location	User	Value	Reason
Nov-16-2020 13:29:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

**5.d Symptom Present:**

Date	Location	User	Value	Reason
Nov-30-2020 10:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Nov-30-2020 10:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DIARRHEA <b>Symptom Present::</b> Not Applicable	Initial Entry
Nov-16-2020 13:29:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DIARRHEA <b>Symptom Present::</b>	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)



**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Nov/12/2020

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

**5.e Symptom:**

Date	Location	User	Value	Reason
Nov-16-2020 13:29:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

**5.e Symptom Present:**

Date	Location	User	Value	Reason
Nov-30-2020 10:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.f**

Date	Location	User	Value	Reason
Nov-30-2020 10:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom:</b> NEW OR WORSE ENED MUSCLE PAIN <b>Symptom Present:</b> Not Applicable	Initial Entry
Nov-16-2020 13:29:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom:</b> NEW OR WORSE ENED MUSCLE PAIN <b>Symptom Present:</b>	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Nov/12/2020

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

**5.f Symptom:**

Date	Location	User	Value	Reason
Nov-16-2020 13:29:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENERED JOINT PAIN	Initial Entry

**5.f Symptom Present:**

Date	Location	User	Value	Reason
Nov-30-2020 10:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g**

Date	Location	User	Value	Reason
Nov-30-2020 10:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom</b> NEW OR WORSENERED JOINT PAIN <b>Symptom</b> Not Applicable <b>Present::</b>	Initial Entry
Nov-16-2020 13:29:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom</b> NEW OR WORSENERED JOINT PAIN <b>Symptom</b> <b>Present::</b>	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Nov/12/2020

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

**5.g Symptom:**

Date	Location	User	Value	Reason
Nov-16-2020 13:29:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENERD JOI NT PAIN	Initial Entry

**5.g Symptom Present:**

Date	Location	User	Value	Reason
Nov-30-2020 10:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.h**

Date	Location	User	Value	Reason
Nov-30-2020 10:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> CHILLS <b>Symptom Present::</b> Not Applicable	Initial Entry
Nov-16-2020 13:29:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> CHILLS <b>Symptom Present:</b> :	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on Nov/12/2020

**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

**5.h Symptom:**

Date	Location	User	Value	Reason
Nov-16-2020 13:29:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

**5.h Symptom Present:**

Date	Location	User	Value	Reason
Nov-30-2020 10:58:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Nov-04-2020 09:51:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/4/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Nov-04-2020 09:51:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Nov-04-2020 09:51:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Nov-04-2020 16:09:22 (UTC-07:00) Mountain 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:** 1048

**Subject No:** 10481104

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Dec-16-2020 16:07:40 (UTC-07:00) Mountain 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: 1048

Subject No: 10481104

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

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**1. Category:**

Date	Location	User	Value	Reason
Nov-04-2020 16:09:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Nov-04-2020 16:09:22 (UTC-07:00) Mountain 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
Nov-04-2020 16:09:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FATIGUE	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Nov-04-2020 16:09:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/11/2020 07:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Nov-04-2020 16:09:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Sep/12/2020 07:00	Initial Entry

**6. Toxicity Grade:**

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)



Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481104

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-04-2020 16:09:22 (UTC-07:00) Mountain 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
Nov-04-2020 16:09:22 (UTC-07:00) Mountain 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?**

**If Yes, record the type of medication error on the Medication Error Log.**

Date	Location	User	Value	Reason
Nov-04-2020 16:09:22 (UTC-07:00) Mountain 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
Nov-04-2020 16:09:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RELATED	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Nov-04-2020 16:09:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Nov-04-2020 16:09:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Nov-04-2020 16:09:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Nov-04-2020 16:09:22 (UTC-07:00) Mountain 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
Nov-04-2020 16:09:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Answered Queries

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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**1. Category:**

Date	Location	User	Value	Reason
Dec-16-2020 16:07:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Dec-16-2020 16:07:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-12-2021 17:24:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	subject is a physician. Notes in source state the subject attributed her decreased hearing to Covid 19
Mar-08-2021 08:43:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: pls advise how diagnosis made ie subjective vs audiometry. Confirm subject no past history of hearing loss or ear complaints eg tinnitus. Thanks
Dec-16-2020 16:07:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> decreased hearing right ear	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Answered Queries

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481104

Subject Initials: ---

Generated By: (b) (4)

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

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-16-2020 16:07:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/30/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-12-2021 17:22:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Jan/21/2021 UNK:UNK	New Information
Dec-16-2020 16:07:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-16-2020 16:07:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Dec-16-2020 16:07:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

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Form Status: Data Complete, Answered Queries

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481104

Subject Initials: ---

Generated By: (b) (4)

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

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Dec-16-2020 16:07:40 (UTC-07:00) Mountain 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
Dec-16-2020 16:07:40 (UTC-07:00) Mountain 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  If Other, specify:  covid-19	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-16-2020 16:07:40 (UTC-07:00) Mountain 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-12-2021 17:24:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Mar-08-2021 08:44:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: pls confirm no medication given for condition.

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Answered Queries

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481104

Subject Initials: ---

Generated By: (b) (4)

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

Dec-16-2020 16:07:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Dec-16-2020 16:07:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Mar-12-2021 17:25:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-12-2021 17:25:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Transcription Error
Mar-12-2021 17:22:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE decreased hearing right ear: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Dec-16-2020 16:07:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RECOVERED/NOT RESOLVED	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Answered Queries

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

Date	Location	User	Value	Reason
Dec-16-2020 16:07:40 (UTC-07:00) Mountain 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:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Jan-20-2021 14:55:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/18/2020	New Information
Jan-07-2021 11:32:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/30/2020	Initial Entry



**Header Text:** c4591001

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

**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit  
Trail History

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

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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***1. Select appropriate response - Is participant willing to return for Vaccination 3?***

Date	Location	User	Value	Reason
Jan-13-2021 09:01:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-07-2021 22:53:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-07-2021 11:41:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-07-2021 11:41:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1048

**Subject No:** 10481104

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

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

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**I. Date of Visit**

Date	Location	User	Value	Reason
Jan-19-2021 23:40:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-19-2021 13:58:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Jan-19-2021 03:28:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly consider to update missing REVAX CONS, SWAB PFE and SAMP TRK forms or else clarify. Thank you.
Jan-07-2021 11:42:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/30/2020	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INFORMED CONSENT - FURTHER VACCINATION -  
eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:31

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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**I. Consent Was:**

Date	Location	User	Value	Reason
Jan-19-2021 13:57:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtai ned  Dec/30/2020	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:31

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

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

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

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

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Jan-07-2021 11:54:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/30/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-07-2021 11:54:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Jan-07-2021 11:54:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

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

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481104

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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3. Collection Date:

Date	Location	User	Value	Reason
Jan-07-2021 12:01:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Jan-07-2021 11:59:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-07-2021 11:59:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-07-2021 11:59:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
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090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:23

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

Jan-07-2021 11:59:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**6.a Not Done:**

Date	Location	User	Value	Reason
Jan-07-2021 11:59:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

Header Text: c4591001

Visit: V101\_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481104

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-19-2021 13:57:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-19-2021 13:57:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-19-2021 13:57:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-19-2021 13:57:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-19-2021 13:57:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Dec/30/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481104

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Jan-19-2021 13:57:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPVSM5	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Jan-19-2021 13:57:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPVSM5	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-02-2021 13:42:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BS69HJ	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-02-2021 13:42:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BS69HJ	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-02-2021 13:42:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BS69HK	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)



**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1048

**Subject No:** 10481104

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

**5.c Sample ID**

Date	Location	User	Value	Reason
Mar-02-2021 13:42:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BS69HK	Initial Entry

Header Text: c4591001

Visit: V101\_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481104

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-19-2021 13:56:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-19-2021 13:56:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-19-2021 13:56:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-19-2021 13:56:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-19-2021 13:56:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Dec/30/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

Jan-19-2021 13:56:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRJ863	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-19-2021 13:56:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRJ863	Initial Entry

Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1048

Subject No: 10481104

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Jan-07-2021 12:04:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jan-07-2021 12:04:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jan-07-2021 12:04:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Jan-07-2021 12:04:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/30/2020 12:15	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jan-07-2021 12:04:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
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090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481104

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Jan-07-2021 12:04:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry
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**7. Route:**

Date	Location	User	Value	Reason
Jan-07-2021 12:04:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**8. Actual Dose:**

Date	Location	User	Value	Reason
Jan-07-2021 12:04:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Jan-07-2021 12:04:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Jan-07-2021 12:04:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

**11. Was the subject observed for at least the protocol specified observation period after investigational product administration?**

Date	Location	User	Value	Reason
Jan-07-2021 12:04:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1048

**Subject No:** 10481104

**Generated By:** (b) (4)

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Jan-20-2021 14:56:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/24/2020	New Information
Jan-13-2021 09:01:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/30/2020	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Jan-13-2021 09:01:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATI ON	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1048

**Subject No:** 10481104

**Generated By:** (b) (4)

**Form:** WITHDRAWAL OF CONSENT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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**1. Withdrawal of Consent Date :**

Date	Location	User	Value	Reason
Jan-13-2021 09:01:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

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**1. Date of Collection / Notification of Death:**

Date	Location	User	Value	Reason
Jan-13-2021 09:02:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry



**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1048

**Subject No:** 10481104

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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**I. Date of Visit**

Date	Location	User	Value	Reason
Jan-28-2021 23:56:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-28-2021 12:42:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Jan-28-2021 07:15:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly review and complete 'Nasal Swab form' at this visit. Thank you.
Jan-20-2021 11:30:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/20/2021	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:23

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-20-2021 11:29:54 (UTC-07:00) Mountain 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
Jan-20-2021 11:29:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Jan-20-2021 11:29:54 (UTC-07:00) Mountain 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
Jan-20-2021 11:29:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Jan-20-2021 11:29:54 (UTC-07:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481104

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

Mountain Time (US & Canada)

(b) (4), (b) (6)

6.a

Date	Location	User	Value	Reason
Jan-20-2021 11:29:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-20-2021 11:29:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-20-2021 11:29:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jan-20-2021 11:29:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:23

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

**6.a Not Done:**

Date	Location	User	Value	Reason
Jan-20-2021 11:29:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

Header Text: c4591001

Visit: V102\_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1048

Site Name: (1048) The Pain Center of Arizona

Subject No: 10481104

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 19-Apr-2021 21:04

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-28-2021 12:41:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-28-2021 12:41:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-28-2021 12:41:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-28-2021 12:41:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-28-2021 12:41:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/20/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

Jan-28-2021 12:41:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRJ86T	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-28-2021 12:41:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRJ86T	Initial Entry

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1048

Subject No: 10481104

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Jan-20-2021 11:30:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jan-20-2021 11:30:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jan-20-2021 11:30:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Jan-20-2021 11:30:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/20/2021 10:06	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jan-20-2021 11:30:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1048

Subject No: 10481104

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1048) The Pain Center of Arizona

Subject Initials: ---

Generated Time (GMT): 19-Apr-2021 21:04

Date	Location	User	Value	Reason
Jan-20-2021 11:30:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Jan-20-2021 11:30:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**8. Actual Dose:**

Date	Location	User	Value	Reason
Jan-20-2021 11:30:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Jan-20-2021 11:30:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Jan-20-2021 11:30:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

**11. Was the subject observed for at least the protocol specified observation period after investigational product administration?**

Date	Location	User	Value	Reason
Jan-20-2021 11:30:41 (UTC-07:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)



**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1048

**Subject No:** 10481104

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

Mountain Time (US & Canada)		(b) (4), (b) (6)		
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**Header Text:** c4591001

**Visit:** V103\_MONTH1

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1048

**Subject No:** 10481104

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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*1. Date of Visit*

Date	Location	User	Value	Reason
Mar-12-2021 17:36:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/8/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V103\_MONTH1

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1048

**Subject No:** 10481104

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

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**1. Contact Type:**

Date	Location	User	Value	Reason
Mar-12-2021 17:36:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Mar-12-2021 17:36:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact:  Mar/8/2021	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** FURTHER\_VACCINATION\_EOT -  
Unscheduled

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Version:** 20-Feb-2021 02:26

**Form Status:** Data Complete, Verified

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Mar-12-2021 17:37:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/8/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Mar-12-2021 17:37:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> OPEN LABEL TREATMENT	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Mar-12-2021 17:37:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Verified

**Site No:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

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**1. Subject Status**

Date	Location	User	Value	Reason
Nov-04-2020 09:51:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Sep-11-2020 18:00:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Sep-11-2020 15:12:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Mar-13-2021 00:17:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-12-2021 17:38:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Mar-04-2021 01:30:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: V103 overdue based on expected visit window. Please enter data or, if visit will never occur, mark Date of Visit as Not Done with form level comment. If subject is no longer in the trial, complete the Disposition FUP form &

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1048

**Subject No:** 10481104

**Generated By:** (b) (4)

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1048) The Pain Center of Arizona

**Subject Initials:** ---

**Generated Time (GMT):** 19-Apr-2021 21:04

				Disposition-Treatment(EOT2)
Nov-04-2020 09:51:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Nov/4/2020	Initial Entry
Sep-11-2020 18:00:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/9/2020	Initial Entry
Sep-11-2020 15:12:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/9/2020	Initial Entry

090177e196d89025\Final\Final On: 22-Apr-2021 02:12 (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:** 1048

**Site Name:** (1048) The Pain Center of Arizona

**Subject No:** 10481104

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 19-Apr-2021 21:04

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*I. Casebook Signature*

Date	Location	User	Value	Reason
Nov-06-2020 09:19:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry