

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** COHORT\_SELECTION

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[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

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** MAIN INFORMED CONSENT

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/13/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** DEMOGRAPHY

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[11261017]
2.	Birth Date:	(b) (6) 1985
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:	

<b>Header Text:</b> c4591001	<b>Form:</b> DATE OF VISIT
<b>Visit:</b> V1_DAY1_VAX1_L	<b>Form Status:</b> Data Complete, Locked, Frozen, Verified
<b>Form Version:</b> 22-Apr-2020 21:02	<b>Site Name:</b> (1126) Kaiser Permanente Santa Clara
<b>Site No:</b> 1126	<b>Subject Initials:</b> ---
<b>Subject No:</b> 11261017	<b>Generated Time (GMT):</b> 29-Mar-2021 11:09
<b>Generated By:</b> (b) (4)	

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Aug/13/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**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 _____
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**Header Text:** c4591001

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

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation /Death	Aug/13/2020
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: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Major Depression, in full remission]
	Start Date:	Mar/21/2014
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Migraine with Aura]
	Start Date:	Jul/15/2018
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Intermittent Asthma]
	Start Date:	Mar/31/2015
	Ongoing:	NO End Date: Mar/1/2018
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Insect Venom Allergic Reaction]
	Start Date:	Mar/13/2015
	Ongoing:	NO End Date: Mar/20/2015
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	Jun/18/2015
	Ongoing:	NO End Date: Jun/1/2016

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**Header Text:** c4591001

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

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Iron Deficiency without Anemia]
	Start Date:	Oct/1/2015
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Coagulopathy, Unspecified Type]
	Start Date:	Mar/1/2019
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Cervical High Risk HPV test positive]
	Start Date:	Apr/5/2019
	Ongoing:	NO End Date: Jun/28/2019
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Allergy to Bee Venom]
	Start Date:	Mar/13/2015
	Ongoing:	YES

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**Header Text:** c4591001

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

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Aug/13/2020
2.	Weight:	[59.1]
3.	Unit:	kg
4.	Height:	[162.0]
5.	Unit:	cm
6.	Body Mass Index:	[22.5]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[99.2]
	Unit:	F
	Temperature Location:	ORAL CAVITY

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**Header Text:** c4591001

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

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/13/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

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**Header Text:** c4591001

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

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** RANDOMIZATION

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Aug/13/2020
2.	Randomization Number:	[48228]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/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	[BP567K]
5.b	Sample ID	[BP567L]
5.c	Sample ID	[BP567M]
5.d	Sample ID	[BPRVZJ]
5.e	Sample ID	[BPRVZK]

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**Header Text:** c4591001

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

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

**Site No:** 1126

**Subject No:** 11261017

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

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

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/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	[BP56KB]
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**Header Text:** c4591001

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

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** VACCINATION

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**eCRF Audit Trail History**

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/13/2020 12:09
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

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**Header Text:** c4591001

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

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** DATE OF VISIT

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Date of Visit**

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



Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

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

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Vital Signs**

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

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

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/1/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1126

**Subject No:** 11261017

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

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

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/1/2020
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	[BP56NW]
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090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** VACCINATION

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**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/1/2020 12:32
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

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (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:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Date of Visit**

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

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

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

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**Header Text:** c4591001

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

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

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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

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**Header Text:** c4591001

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

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/1/2020
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	[BP28JN]
5.b	Sample ID	[BPRW98]
5.c	Sample ID	[BLC38N]

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/21/2020

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

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/21/2020
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  
Oct/21/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Signs and Symptoms**

1.	Date of Assessment:	Oct/21/2020
2.	Date of First Symptom Started:	Oct/20/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Nov/20/2020

**Symptoms**

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

**Symptoms - Other**

5.	Symptoms - Other Text:	[ ]
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090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

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

**Form:** MICROBIOLOGY SPECIMEN

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Oct/20/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/21/2020

**Form:** MICROBIOLOGY SPECIMEN

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Microbiology Specimen**

1.	Actual Date of Collection:	Oct/20/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[ ]
9.	Trade Name Other, Specify:	[CORONAVIR PAN-2019 NCOV, NAA, QL (KAISER CLIA LAB)]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/21/2020

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

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Oct/21/2020
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	[RW82931]
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090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/21/2020

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

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

[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:	[SEE SELF SWAB]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/21/2020

**Form:** HEALTH CARE UTILIZATION

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Health Care Utilization**

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

**Health Care Utilization Other**

2.	Other Type of Practitioner Specify:	[ ]
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**Health Care Utilization**

3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO
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090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

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

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020      **Form:** RESPIRATORY TREATMENT

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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[eCRF Audit Trail History](#)

**Respiratory Treatment**

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

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/21/2020

**Form:** ILLNESS DETAILS

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Illness Details**

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

**Header Text:** c4591001

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

**Form:** ILLNESS DETAILS - SEVERE

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/21/2020

**Form:** ILLNESS DETAILS - SEVERE

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Illness Details**

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

Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 30-Jul-2020 21:27

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/21/2020

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

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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[Form Comments](#)

[eCRF Audit Trail History](#)

**Lab Chemistry Details**

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

**Lab Result**

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

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/21/2020

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

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

5.b	Sponsor ID:	Not Done _____	<a href="#">Comments</a>
		[ ]	
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Done _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Done _____	<a href="#">Comments</a>	
LNMT	Not Done _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		
5.c	Sponsor ID:	Not Done _____	<a href="#">Comments</a>
		[ ]	
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Done _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Done _____	<a href="#">Comments</a>	
LNMT	Not Done _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/21/2020

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

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

5.d	Sponsor ID:	Not Done _____	<a href="#">Comments</a>
		[ ]	
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Done _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Done _____	<a href="#">Comments</a>	
LNMT	Not Done _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		
5.e	Sponsor ID:	Not Done _____	<a href="#">Comments</a>
		[ ]	
	Test:	Bilirubin_PX21	
	Result:	Not Done _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Done _____	<a href="#">Comments</a>	
LNMT	Not Done _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/21/2020

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

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

5 f	Sponsor ID:	Not Done _____	<a href="#">Comments</a>
		[ ]	
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Done _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Done _____	<a href="#">Comments</a>	
LNMT	Not Done _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		
5.g	Sponsor ID:	Not Done _____	<a href="#">Comments</a>
		[ ]	
	Test:	Creatinine_PX48	
	Result:	Not Done _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Done _____	<a href="#">Comments</a>	
LNMT	Not Done _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/21/2020

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

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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[eCRF Audit Trail History](#)

**Laboratory Data Hematology**

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

**Lab Result**

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

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

5.b	Sponsor ID:	Not Done _____	<a href="#">Comments</a>
		[ ]	
	Test:	Hematocrit_PX2	
	Result:	Not Done _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Done _____	<a href="#">Comments</a>	
LNMT	Not Done _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		
5.c	Sponsor ID:	Not Done _____	<a href="#">Comments</a>
		[ ]	
	Test:	Erythrocytes_PX3	
	Result:	Not Done _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Done _____	<a href="#">Comments</a>	
LNMT	Not Done _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

5.d	Sponsor ID:	Not Done _____	<a href="#">Comments</a>
		[ ]	
	Test:	Platelets_PX5	
	Result:	Not Done _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Done _____	<a href="#">Comments</a>	
LNMT	Not Done _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		
5.e	Sponsor ID:	Not Done _____	<a href="#">Comments</a>
		[ ]	
	Test:	Leukocytes_PX7	
	Result:	Not Done _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Done _____	<a href="#">Comments</a>	
LNMT	Not Done _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

5 f	Sponsor ID:	Not Done _____	<a href="#">Comments</a>
		[ ]	
	Test:	Neutrophils_PX608	
	Result:	Not Done _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Done _____	<a href="#">Comments</a>	
LNMT	Not Done _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		
5.g	Sponsor ID:	Not Done _____	<a href="#">Comments</a>
		[ ]	
	Test:	Eosinophils_PX609	
	Result:	Not Done _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Done _____	<a href="#">Comments</a>	
LNMT	Not Done _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

5.h	Sponsor ID:	Not Done _____	<a href="#">Comments</a>
		[ ]	
	Test:	Monocytes_PX612	
	Result:	Not Done _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Done _____	<a href="#">Comments</a>	
LNMT	Not Done _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		
5.i	Sponsor ID:	Not Done _____	<a href="#">Comments</a>
		[ ]	
	Test:	Basophils_PX610	
	Result:	Not Done _____	<a href="#">Comments</a>
		[ ]	
Not Done:	Not Done _____	<a href="#">Comments</a>	
LNMT	Not Done _____	<a href="#">Comments</a>	
	Low [ ] High [ ] Unit		

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

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

**Form:** VITAL SIGNS - COVID

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

#	Date:	Vital Signs Details			Form Instance					
1.	Oct/20/2020	<table border="1"><thead><tr><th>Record Identifier:</th><th>Systolic:</th><th>Diastolic:</th></tr></thead><tbody><tr><td>1</td><td>141</td><td>92</td></tr></tbody></table>	Record Identifier:	Systolic:	Diastolic:	1	141	92	<a href="#">Repeating Pages</a>	
Record Identifier:	Systolic:	Diastolic:								
1	141	92								

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/21/2020

**Form:** VITAL SIGNS - COVID

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Vital Signs**

1.	Date:	Oct/20/2020
----	-------	-------------

**Vital Signs Details**

2.a	Record Identifier:	1
	Systolic:	[141]
	Diastolic:	[92]
	Respiratory Rate in respirations/minute:	[18]
	Heart Rate in beats/minute:	[99]

**Header Text:** c4591001

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

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

#	Date:	Vital Signs Details		Form Instance
1.	Oct/20/2020	<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>
		1	100.0	

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/21/2020

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

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Vital Signs**

1.	Date:	Oct/20/2020
----	-------	-------------

**Vital Signs Details**

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[100.0]

**Header Text:** c4591001

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

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/21/2020

**Form:** OXYGENATION PARAMETERS

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Oxygenation Parameters**

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



**Header Text:** c4591001

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

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/21/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Concomitant Medications**

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

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

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

**Form:** IMAGING

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** IMAGING  
Oct/21/2020

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Imaging**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled Visit    **Form:** DATE OF VISIT - ILLNESS CONVALESCENT  
on Nov/24/2020

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Date of Visit**

1.	Date of Visit	Nov/24/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
on Nov/24/2020

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/24/2020
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	[BPZZ04]
5.b	Sample ID	[BLC38G]
5.c	Sample ID	[BLC3HW]

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Nov/24/2020

**Form:** DATE OF VISIT

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Date of Visit**

			<a href="#">Comments</a>
1.	Date of Visit	Nov/24/2020	
2.	Erroneous Visit	ERRONEOUS VISIT	

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Nov/24/2020

**Form:** UNPLANNED VISIT

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

**Form Status:** Not Started

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

**Unplanned Assessments**

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



**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:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Oct/1/2020
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:** 1126

**Subject No:** 11261017

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

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**Disposition - Follow-Up**

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

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	
<b>COVID-19 Repeat Swab</b>		
3.	COVID-19 Repeat Swab:	

**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Acute sinusitis	Aug/15/2020 04:00	NO End Date Time: Aug/20/2020 12:00	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	VACCINE ALLERGIC REACTION	Jan/7/2021 11:37	NO End Date Time: Jan/8/2021 UNK:UNK	<a href="#">Repeating Pages</a>
3.	ADVERSE EVENT	3	Facial Flushing	Jan/7/2021 11:37	NO End Date Time: Jan/8/2021 UNK:UNK	<a href="#">Repeating Pages</a>
4.	ADVERSE EVENT	4	Facial swelling	Jan/7/2021 11:37	NO End Date Time: Jan/8/2021 UNK:UNK	<a href="#">Repeating Pages</a>
5.	ADVERSE EVENT	5	Hives, abdomen	Jan/7/2021 14:50	NO End Date Time: Jan/8/2021 UNK:UNK	<a href="#">Repeating Pages</a>
6.	ADVERSE EVENT	6	Nausea	Jan/7/2021 12:50	NO End Date Time: Jan/7/2021 14:00	<a href="#">Repeating Pages</a>
7.	ADVERSE EVENT	7	Muscle aches	Jan/8/2021 UNK:UNK	NO End Date Time: Jan/9/2021 UNK:UNK	<a href="#">Repeating Pages</a>

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

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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)	[Acute sinusitis]
4.	Start Date Time:	Aug/15/2020 04:00
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/20/2020 12:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [UNKNOWN]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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 - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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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)	[VACCINE ALLERGIC REACTION]
4.	Start Date Time:	Jan/7/2021 11:37
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/8/2021 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
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	DRUG WITHDRAWN
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
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

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]
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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Facial Flushing]
4.	Start Date Time:	Jan/7/2021 11:37
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/8/2021 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
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
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

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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**Site No:** 1126

**Subject No:** 11261017

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

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15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]
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**Visit:** Logs - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Facial swelling]
4.	Start Date Time:	Jan/7/2021 11:37
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/8/2021 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
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
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

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**Header Text:** c4591001

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**Site No:** 1126

**Subject No:** 11261017

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]
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090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Hives, abdomen]
4.	Start Date Time:	Jan/7/2021 14:50
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/8/2021 UNK:UNK
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
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
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

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]
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090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Nausea]
4.	Start Date Time:	Jan/7/2021 12:50
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/7/2021 14:00
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
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
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

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]
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090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[7]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Muscle aches]
4.	Start Date Time:	Jan/8/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/9/2021 UNK:UNK
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
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

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

#	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:** 1126

**Subject No:** 11261017

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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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	[ ]

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	Influenza vaccine (Fluarix quadrivalent)	Sep/21/2020	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261017

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

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

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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**Concomitant Medications**

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication:  Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Influenza vaccine (Fluarix quadrivalent)]
5.	Date:	Sep/21/2020

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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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:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

#	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:** 1126

**Subject No:** 11261017

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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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?	

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

#	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:** 1126

**Subject No:** 11261017

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

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

**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:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

**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:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

**Lab Urinalysis**

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[ ]
5.	Specimen Type:	

**Lab Result**

6.	Sponsor ID:	[ ]
	Test:	
	Result:	
	Not Done:	



**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

**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?	

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** CONTACT OUTCOME - MONTH 1

**Form Status:** Not Started

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** CONTACT OUTCOME - MONTH 6

**Form Status:** Not Started

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**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:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Dec/21/2020
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:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

[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
----	---	---

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** DATE OF VISIT

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/7/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** INFORMED CONSENT - FURTHER VACCINATION

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Informed Consent - Further Vaccination**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/7/2021
----	--------------	---

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1126

**Subject No:** 11261017

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

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

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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

**Site No:** 1126

**Subject No:** 11261017

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

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

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

1.	Date of Completion/Discontinuation /Death :	Jan/7/2021
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:** 1126

**Subject No:** 11261017

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jan/7/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/7/2021
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	[BPZZ7S]
5.b	Sample ID	[BS7VKR]
5.c	Sample ID	[BLC3LV]

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1126

**Subject No:** 11261017

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

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

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/7/2021
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	[BP294K]
-----	-----------	----------

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** VACCINATION

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**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/7/2021 11:32
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

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** TREATMENT UNBLINDED

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Dec/21/2020
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:** 1126

**Subject No:** 11261017

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

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**Withdrawal Of Consent**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**Death Details**

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

**Cause of Death**

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



**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** DATE OF VISIT

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Date of Visit**

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

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

[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>

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1126

**Subject No:** 11261017

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

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

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR7YWY]
-----	-----------	----------

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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

**Vaccination**

1.	Was there a temporary delay of vaccination?	Not Done _____	<a href="#">Comments</a>
2.	Treatment Name	Not Done _____ [ ]	<a href="#">Comments</a>
3.	Formulation:	Not Done _____	<a href="#">Comments</a>
4.	Dose Date Time:	Not Done _____ //	<a href="#">Comments</a>
5.	Anatomical Location:	Not Done _____	<a href="#">Comments</a>
6.	Body Side:	Not Done _____	<a href="#">Comments</a>
7.	Route:	Not Done _____	<a href="#">Comments</a>
8.	Actual Dose:	Not Done _____ [ ]	<a href="#">Comments</a>
9.	Unit:	Not Done _____	<a href="#">Comments</a>
10.	Timeframe Subject Was Observed	Not Done _____	<a href="#">Comments</a>
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	Not Done _____	<a href="#">Comments</a>

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

<b>Header Text:</b> c4591001	<b>Form:</b> DATE OF VISIT
<b>Visit:</b> V103_MONTH1	<b>Form Status:</b> Data Complete, Frozen, Verified
<b>Form Version:</b> 22-Apr-2020 21:02	<b>Site Name:</b> (1126) Kaiser Permanente Santa Clara
<b>Site No:</b> 1126	<b>Subject Initials:</b> ---
<b>Subject No:</b> 11261017	<b>Generated Time (GMT):</b> 29-Mar-2021 11:09
<b>Generated By:</b> (b) (4)	

[eCRF Audit Trail History](#)

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

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** CONTACT OUTCOME

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Feb/25/2021
3.	Comments:	[ ]

**Header Text:** c4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**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:** 1126

**Subject No:** 11261017

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

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**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:** 1126

**Subject No:** 11261017

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

<b>Header Text:</b> c4591001	<b>Form:</b> CONTACT OUTCOME
<b>Visit:</b> V105_MONTH18	<b>Form Status:</b> Not Started
<b>Form Version:</b> 22-Apr-2020 21:04	<b>Site Name:</b> (1126) Kaiser Permanente Santa Clara
<b>Site No:</b> 1126	<b>Subject Initials:</b> ---
<b>Subject No:</b> 11261017	<b>Generated Time (GMT):</b> 29-Mar-2021 11:09
<b>Generated By:</b> (b) (4)	

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

**Header Text:** c4591001

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

**Form:** DISPOSITION - TREATMENT

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Jan/28/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	ADVERSE EVENT
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Subject Status**

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

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** CASEBOOK SIGNATURE FORM

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Nicola Klein	Approved	Mar-08-2021 16:43:05 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

**Affidavit:**

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

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

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

**Header Text:** c4591001

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

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

**Site No:** 1126

**Subject No:** 11261017

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

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

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
Form	Aug-13-2020 13:58:01 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/21/2020

**Form:** RESPIRATORY TREATMENT - Comments

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
Form	Oct-21-2020 19:55:24 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

**Form:** RESPIRATORY TREATMENT - Comments

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
1	Oct-21-2020 19:55:24 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

**Form:** RESPIRATORY TREATMENT - Comments

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
2	Oct-21-2020 19:55:24 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

**Form:** RESPIRATORY TREATMENT - Comments

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
3	Oct-21-2020 19:55:24 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

**Form:** RESPIRATORY TREATMENT - Comments

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
4	Oct-21-2020 19:55:24 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

**Form:** RESPIRATORY TREATMENT - Comments

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
5	Oct-21-2020 19:55:24 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

**Form:** RESPIRATORY TREATMENT - Comments

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
6	Oct-21-2020 19:55:24 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

**Form:** ILLNESS DETAILS - SEVERE - Comments

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
Form	Oct-21-2020 19:54:40 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

**Form:** ILLNESS DETAILS - SEVERE - Comments

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
1	Oct-21-2020 19:54:40 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

**Form:** ILLNESS DETAILS - SEVERE - Comments

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
2	Oct-21-2020 19:54:40 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

**Form:** ILLNESS DETAILS - SEVERE - Comments

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

[Back to Form](#)

Item	Date	User	Comment
3	Oct-21-2020 19:54:40 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

**Form:** ILLNESS DETAILS - SEVERE - Comments

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

[Back to Form](#)

Item	Date	User	Comment
4	Oct-21-2020 19:54:40 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

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

**Site No:** 1126

**Subject No:** 11261017

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

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

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
Form	Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

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

**Site No:** 1126

**Subject No:** 11261017

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

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

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[Back to Form](#)

Item	Date	User	Comment
1	Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) ( )	Not Done

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

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

**Site No:** 1126

**Subject No:** 11261017

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

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

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

[Back to Form](#)

Item	Date	User	Comment
2	Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

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

**Site No:** 1126

**Subject No:** 11261017

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

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

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
3	Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

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

**Site No:** 1126

**Subject No:** 11261017

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

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

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
4	Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

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

**Site No:** 1126

**Subject No:** 11261017

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

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

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
5.a	Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

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**Subject No:** 11261017

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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

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**Subject Initials:** ---

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Form	Oct-21-2020 19:57:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

**Form:** OXYGENATION PARAMETERS - Comments

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
1	Oct-21-2020 19:57:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

**Form:** OXYGENATION PARAMETERS - Comments

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
2	Oct-21-2020 19:57:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

**Form:** OXYGENATION PARAMETERS - Comments

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
3	Oct-21-2020 19:57:07 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
Form	Oct-21-2020 19:57:18 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
1	Oct-21-2020 19:57:18 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
2	Oct-21-2020 19:57:18 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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

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Item	Date	User	Comment
3	Oct-21-2020 19:57:18 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

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

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Item	Date	User	Comment
4	Oct-21-2020 19:57:18 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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

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**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
5	Oct-21-2020 19:57:18 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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

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

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**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
6	Oct-21-2020 19:57:18 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020      **Form:** IMAGING - Comments

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
Form	Oct-21-2020 19:57:30 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020      **Form:** IMAGING - Comments

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
1	Oct-21-2020 19:57:30 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020      **Form:** IMAGING - Comments

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
2	Oct-21-2020 19:57:30 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020      **Form:** IMAGING - Comments

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
3	Oct-21-2020 19:57:30 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020 **Form:** IMAGING - Comments

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
4	Oct-21-2020 19:57:30 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** DATE OF VISIT - Comments

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
1	Nov-25-2020 15:12:16 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Data entry error, visit has not occurred

**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:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
Form	Jan-08-2021 13:07:38 (UTC-08:00) Pacific Time (US & Canada)	Charlie Chao (b) (4)	N/A Not Applicable

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1126

**Subject No:** 11261017

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

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

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
Form	Jan-29-2021 12:38:54 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	N/A Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1126

**Subject No:** 11261017

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

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

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
1	Jan-29-2021 12:38:54 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	N/A
			Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1126

**Subject No:** 11261017

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

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

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
2	Jan-29-2021 12:38:54 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	N/A
			Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1126

**Subject No:** 11261017

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

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

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
3	Jan-29-2021 12:38:54 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	N/A
			Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1126

**Subject No:** 11261017

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

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

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
4	Jan-29-2021 12:38:54 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	N/A
			Not Applicable



**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1126

**Subject No:** 11261017

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

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

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
5	Jan-29-2021 12:38:54 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	N/A
			Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1126

**Subject No:** 11261017

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

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

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
6.a	Jan-29-2021 12:38:54 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	N/A
			Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1126

**Subject No:** 11261017

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

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

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
6.a	Jan-29-2021 12:38:54 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	N/A
			Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1126

**Subject No:** 11261017

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

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

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
6.a	Jan-29-2021 12:38:54 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	N/A
			Not Applicable

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
Form	Mar-01-2021 13:56:21 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Subject did not get vaccinated. Due to meeting Exclusion Criteria # 3.
Form	Feb-11-2021 08:13:23 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
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1	Feb-04-2021 12:21:40 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** V102\_VAX4

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**Form:** VACCINATION - Comments

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Item	Date	User	Comment
2	Feb-11-2021 08:13:23 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

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**Header Text:** c4591001

**Visit:** V102\_VAX4

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

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Item	Date	User	Comment
3	Feb-11-2021 08:13:23 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done



**Header Text:** c4591001

**Visit:** V102\_VAX4

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

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**Site Name:** (1126) Kaiser Permanente Santa Clara

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**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
4	Feb-11-2021 08:13:23 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done
4	Feb-02-2021 14:59:22 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done
4	Jan-29-2021 12:42:05 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	N/A Not Applicable

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Item	Date	User	Comment
5	Feb-11-2021 08:13:23 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

**Header Text:** c4591001

**Visit:** V102\_VAX4

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Item	Date	User	Comment
6	Feb-11-2021 08:13:23 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done
6	Feb-02-2021 14:59:35 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done
6	Jan-29-2021 12:40:59 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	N/A Not Applicable

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
7	Feb-11-2021 08:13:23 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

**Header Text:** c4591001

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

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**Subject Initials:** ---

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Item	Date	User	Comment
8	Feb-11-2021 08:13:23 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

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**Subject No:** 11261017

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

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**Subject Initials:** ---

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Item	Date	User	Comment
9	Feb-11-2021 08:13:23 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
10	Feb-11-2021 08:13:23 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Done

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Item	Date	User	Comment
11	Feb-11-2021 08:13:23 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done
11	Feb-08-2021 17:35:17 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Nicola Klein	Approved	Mar-08-2021 16:43:05 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

**Affidavit:**

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

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

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

(b) (6)	N/A	Jan-29-2021 12:38:04 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Nicola Klein	Approved	Jan-22-2021 10:56:51 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, NicolaKlein, 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-27-2020 21:40:11 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Nicola Klein	Approved	Dec-01-2020 13:54:27 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

**Affidavit:**

By my dated signature below, I, NicolaKlein, 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-25-2020 15:11:41 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Nicola Klein	Approved	Oct-22-2020 14:59:43 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Oct-21-2020 19:52:13 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Nicola Klein	Approved	Oct-13-2020 12:11:54 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, NicolaKlein, 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.

Charlie Chao	N/A	Oct-01-2020 16:52:37 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

**Affidavit:**

N/A

Nicola Klein	Approved	Sep-10-2020 16:02:02 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, NicolaKlein, 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.

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** COHORT\_SELECTION - eCRF Audit Trail History

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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**1. Select appropriate response - Protocol version**

Date	Location	User	Value	Reason
Aug-13-2020 13:57:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 13:57:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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**I. Consent Was:**

Date	Location	User	Value	Reason
Aug-13-2020 13:57:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Aug/13/2020	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Subject ID**

Date	Location	User	Value	Reason
Aug-13-2020 13:57:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11261017	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-13-2020 13:57:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) 1985	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-13-2020 13:57:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Aug-13-2020 13:57:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 13:57:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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*I. Date of Visit*

Date	Location	User	Value	Reason
Aug-13-2020 13:57:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Aug/13/2020	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Aug-13-2020 13:58:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/13/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-13-2020 13:58:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Aug-13-2020 13:58:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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*I.a*

Date	Location	User	Value	Reason
Aug-13-2020 13:58:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Num</b> 1 <b>ber:</b> <b>Medical Histor</b> Major Depression, in f <b>y Term:</b> ull remission <b>Start Date:</b> Mar/21/2014 <b>Ongoing:</b> YES	Initial Entry

*I.a Line/MH Number:*

Date	Location	User	Value	Reason
Aug-13-2020 13:58:37 (UTC-08:00) Pacific 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
Aug-13-2020 13:58:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Major Depression, in full remission	Initial Entry

*I.a Start Date:*

Date	Location	User	Value	Reason
Aug-13-2020 13:58:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Mar/21/2014	Initial Entry

*I.a Ongoing:*

Date	Location	User	Value	Reason
Aug-13-2020 13:58:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> YES	Initial Entry

*I.b*

Date	Location	User	Value	Reason
Aug-13-2020 13:58:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 2	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

			<b>Medical History Term:</b> Migraine with Aura <b>Start Date:</b> Jul/15/2018 <b>Ongoing:</b> YES	
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**I.b Line/MH Number:**

Date	Location	User	Value	Reason
Aug-13-2020 13:58:57 (UTC-08:00) Pacific 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
Aug-13-2020 13:58:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Migraine with Aura	Initial Entry

**I.b Start Date:**

Date	Location	User	Value	Reason
Aug-13-2020 13:58:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jul/15/2018	Initial Entry

**I.b Ongoing:**

Date	Location	User	Value	Reason
Aug-13-2020 13:58:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.c**

Date	Location	User	Value	Reason
Aug-13-2020 13:59:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 3 <b>Medical History Term:</b> Intermittent Asthma <b>Start Date:</b> Mar/31/2015 <b>Ongoing:</b> NO End Date: Mar/1/2018	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

**I.c Line/MH Number:**

Date	Location	User	Value	Reason
Aug-13-2020 13:59:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 13:59:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Intermittent Asthma	Initial Entry

**I.c Start Date:**

Date	Location	User	Value	Reason
Aug-13-2020 13:59:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/31/2015	Initial Entry

**I.c Ongoing:**

Date	Location	User	Value	Reason
Aug-13-2020 13:59:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: Mar/1/2018	Initial Entry

**I.d**

Date	Location	User	Value	Reason
Aug-13-2020 14:00:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 4 <b>Medical History Term:</b> Insect Venom Allergic Reaction <b>Start Date:</b> Mar/13/2015 <b>Ongoing:</b> NO End Date: Mar/20/2015	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

**I.d Line/MH Number:**

Date	Location	User	Value	Reason
Aug-13-2020 14:00:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 14:00:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Insect Venom Allergic Reaction	Initial Entry

**I.d Start Date:**

Date	Location	User	Value	Reason
Aug-13-2020 14:00:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/13/2015	Initial Entry

**I.d Ongoing:**

Date	Location	User	Value	Reason
Aug-13-2020 14:00:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: Mar/20/2015	Initial Entry

**I.e**

Date	Location	User	Value	Reason
Aug-13-2020 14:02:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 5 <b>Medical History Term:</b> Hypertension <b>Start Date:</b> Jun/18/2015 <b>Ongoing:</b> NO End Date: Jun/1/2016	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

***I.e Line/MH Number:***

Date	Location	User	Value	Reason
Aug-13-2020 14:02:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 14:02:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hypertension	Initial Entry

***I.e Start Date:***

Date	Location	User	Value	Reason
Aug-13-2020 14:02:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jun/18/2015	Initial Entry

***I.e Ongoing:***

Date	Location	User	Value	Reason
Aug-13-2020 14:02:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: Jun/1/2016	Initial Entry

***I.f***

Date	Location	User	Value	Reason
Aug-13-2020 14:02:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 6 <b>Medical History Term:</b> Iron Deficiency without Anemia <b>Start Date:</b> Oct/1/2015 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

***I.f Line/MH Number:***

Date	Location	User	Value	Reason
Aug-13-2020 14:02:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

***I.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Aug-13-2020 14:02:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Iron Deficiency without Anemia	Initial Entry

***I.f Start Date:***

Date	Location	User	Value	Reason
Aug-13-2020 14:02:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/1/2015	Initial Entry

***I.f Ongoing:***

Date	Location	User	Value	Reason
Aug-13-2020 14:02:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***I.g***

Date	Location	User	Value	Reason
Aug-13-2020 14:03:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 7 <b>Medical History Term:</b> Coagulopathy, Unspecified Type <b>Start Date:</b> Mar/1/2019 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

**I.g Line/MH Number:**

Date	Location	User	Value	Reason
Aug-13-2020 14:03:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 08:49:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Carlos Linn (b) (4)	Query 1: Closed	Response satisfies query
Aug-18-2020 18:56:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject has low Von Willibrand Antigen level but did not meet criteria for diagnosis.
Aug-18-2020 10:28:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Carlos Linn (b) (4)	Query 1: Opened	Please clarify more in term of "coagulopathy, unspecific type?" any immunocompromised state related with the coagulopathy?
Aug-13-2020 14:03:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Coagulopathy, Unspecified Type	Initial Entry

**I.g Start Date:**

Date	Location	User	Value	Reason
Aug-13-2020 14:03:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/1/2019	Initial Entry

**I.g Ongoing:**

Date	Location	User	Value	Reason
Aug-13-2020 14:03:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.h**

Date	Location	User	Value	Reason
Aug-13-2020 14:03:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 8	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

			<b>Medical History Term:</b> Cervical High Risk HPV test positive <b>Start Date:</b> Apr/5/2019 <b>Ongoing:</b> NO End Date: Jun/28/2019	
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**I.h Line/MH Number:**

Date	Location	User	Value	Reason
Aug-13-2020 14:03:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 8	Initial Entry

**I.h Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Aug-13-2020 14:03:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Cervical High Risk HPV test positive	Initial Entry

**I.h Start Date:**

Date	Location	User	Value	Reason
Aug-13-2020 14:03:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Apr/5/2019	Initial Entry

**I.h Ongoing:**

Date	Location	User	Value	Reason
Aug-13-2020 14:03:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: Jun/28/2019	Initial Entry

**I.i**

Date	Location	User	Value	Reason
Aug-14-2020 08:10:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Line/MH Number</b> 9 : <b>Medical History Term:</b> Allergy to Bee Venom <b>Start Date:</b> Mar/13/2015	New Information

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

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Generated Time (GMT): 29-Mar-2021 11:09

			Ongoing: YES	
Aug-13-2020 14:04:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 9 <b>Medical History Term:</b> Bee Venom <b>Start Date:</b> Mar/13/2015 <b>Ongoing:</b> YES	Initial Entry

***L.i Line/MH Number:***

Date	Location	User	Value	Reason
Aug-13-2020 14:04:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 9	Initial Entry

***L.i Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Aug-14-2020 09:46:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Aug-14-2020 08:10:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Aug-14-2020 08:10:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Allergy to Bee Venom	New Information
Aug-13-2020 16:04:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify as follows...Please clarify term BEE VENOM. Is this referring to BEE VENOM ALLERGY? BEE VENOM ACUPUNCTURE THERAPY? Please edit term to clarify. Thank you.

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

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

Date	Location	User	Value	Reason
Aug-13-2020 14:04:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Bee Venom	Initial Entry

*1.i Start Date:*

Date	Location	User	Value	Reason
Aug-13-2020 14:04:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Mar/13/2015	Initial Entry

*1.i Ongoing:*

Date	Location	User	Value	Reason
Aug-13-2020 14:04:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:28

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Date:**

Date	Location	User	Value	Reason
Aug-13-2020 14:05:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/13/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-13-2020 14:05:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 59.1	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-13-2020 14:05:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Aug-13-2020 14:05:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 162.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Aug-13-2020 14:05:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Aug-13-2020 14:05:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 22.5	Initial Entry

**7.a**

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:28

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

Aug-13-2020 14:05:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 99.2 <b>Temperature Unit:</b> F <b>Temperature Location::</b> ORAL CAVITY	Initial Entry
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**7.a Record Identifier:**

Date	Location	User	Value	Reason
Aug-13-2020 14:05:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Aug-13-2020 14:05:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 99.2	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Aug-13-2020 14:05:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Aug-13-2020 14:05:48 (UTC-08:00) Pacific 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 Version: 30-Jul-2020 21:27

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Aug-13-2020 14:06:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Aug-13-2020 14:06:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Aug-13-2020 14:06:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Aug/13/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Aug-13-2020 14:06:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Aug-13-2020 14:06:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Aug-13-2020 14:06:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Defined 113 <b>Identifier:</b> Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	Initial Entry

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**Header Text:** c4591001

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

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

**Site No:** 1126

**Subject No:** 11261017

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

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

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Aug-13-2020 14:06:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Aug-13-2020 14:06:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Aug-13-2020 14:06:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

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**Header Text:** c4591001

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

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** RANDOMIZATION - eCRF Audit Trail History

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Aug-13-2020 14:06:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Aug/13/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-13-2020 14:06:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> 48228	Initial Entry

Header Text: c4591001  
 Visit: V1\_DAY1\_VAX1\_L  
 Form Version: 22-Apr-2020 21:03  
 Site No: 1126  
 Subject No: 11261017  
 Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
 Audit Trail History  
 Form Status: Data Complete, Locked, Frozen, Verified  
 Site Name: (1126) Kaiser Permanente Santa Clara  
 Subject Initials: ---  
 Generated Time (GMT): 29-Mar-2021 11:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-13-2020 14:06:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-13-2020 14:06:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-13-2020 14:06:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-13-2020 14:06:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-13-2020 14:06:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> YES Date of Collection: Aug/13/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-13-2020 14:06:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Sample ID:</b> BP567K	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-13-2020 14:06:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> BP567K	Initial Entry

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Header Text: c4591001  
 Visit: V1\_DAY1\_VAX1\_L  
 Form Version: 22-Apr-2020 21:03  
 Site No: 1126  
 Subject No: 11261017  
 Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
 Audit Trail History  
 Form Status: Data Complete, Locked, Frozen, Verified  
 Site Name: (1126) Kaiser Permanente Santa Clara  
 Subject Initials: ---  
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5.b

Date	Location	User	Value	Reason
Aug-13-2020 14:06:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP567L	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-13-2020 14:06:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP567L	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-13-2020 14:07:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP567M	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-13-2020 14:07:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP567M	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-13-2020 14:07:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPRVZJ	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-13-2020 14:07:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPRVZJ	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-13-2020 14:07:23 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPRVZK	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (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:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

(US & Canada)				
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**5.e Sample ID**

Date	Location	User	Value	Reason
Aug-13-2020 14:07:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> BPRVZK	Initial Entry

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261017**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:09[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-13-2020 14:07:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-13-2020 14:07:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-13-2020 14:07:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-13-2020 14:07:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-13-2020 14:07:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> YES Date of Collection:  Aug/13/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-13-2020 14:07:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Sample ID:</b> BP56KB	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-13-2020 14:07:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> BP56KB	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Aug-13-2020 14:08:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Aug-13-2020 14:08:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-13-2020 14:08:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Aug-13-2020 14:08:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/13/2020 12:09	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-13-2020 14:08:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Aug-13-2020 14:08:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
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090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** VACCINATION - eCRF Audit Trail History

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

Aug-13-2020 14:08:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry
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**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Aug-13-2020 14:08:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSER VATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 14:08:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Aug-13-2020 14:08:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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*I. Date of Visit*

Date	Location	User	Value	Reason
Sep-01-2020 16:21:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/1/2020	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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

Date	Location	User	Value	Reason
Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R  <b>Were fever or systemic symptom NO s present on the last day the Sub ject Diary was completed?:</b>	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FAT IGU E  <b>Were fever or systemic sympto NO ms present on the last day the S ubject Diary was completed?:</b>	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)



Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

2.b Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HEA DAC HE <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> CH ILL S	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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

Date	Location	User	Value	Reason
Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: VO MITI NG  Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
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090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b>  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry  DIA RRH EA NO
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2.f Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b>  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry  NEW OR WORSENE D MUSCL E PAIN NO

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

2.g Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENERED MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSENERED JOINT PAIN  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENERED JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RED NES S  <b>Were injection site reactions pr</b> NO <b>esent on the last day the Subjec</b> <b>t Diary was completed?:</b>	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> SWE LLIN G  <b>Were injection site reactions p</b> NO <b>resent on the last day the Subj</b> <b>ect Diary was completed?:</b>	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> PAIN AT INJECTION SITE  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 16:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 21-Aug-2020 02:51

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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**I. Date:**

Date	Location	User	Value	Reason
Sep-01-2020 16:22:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/1/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-01-2020 16:22:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 98.7 <b>Temperature Unit:</b> F <b>Temperature Location:</b> ORAL CAVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-01-2020 16:22:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-01-2020 16:22:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.7	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-01-2020 16:22:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-01-2020 16:22:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 30-Jul-2020 21:27

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-01-2020 16:22:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Sep-01-2020 16:22:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Sep-01-2020 16:22:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/1/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Sep-01-2020 16:22:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Sep-01-2020 16:22:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Sep-01-2020 16:22:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Defined 113 <b>Identifier:</b> Test:: Choriogonadotropin Beta_PX113 <b>Result::</b> NEGATIVE <b>Not Done::</b>	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1126

**Subject No:** 11261017

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

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

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Sep-01-2020 16:22:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Sep-01-2020 16:22:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Sep-01-2020 16:22:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (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:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261017**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:09[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-01-2020 16:22:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-01-2020 16:22:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-01-2020 16:23:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-01-2020 16:22:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-01-2020 16:22:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> YES Date of Collection: Sep/1/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-01-2020 16:23:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Sample ID:</b> BP56NW	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-01-2020 16:23:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> BP56NW	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-01-2020 16:23:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-01-2020 16:23:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-01-2020 16:23:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-01-2020 16:23:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/1/2020 12:32	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-01-2020 16:23:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Sep-01-2020 16:23:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
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090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** VACCINATION - eCRF Audit Trail History

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

Sep-01-2020 16:23:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry
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**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-01-2020 16:23:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSER VATION 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-01-2020 16:23:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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*I. Date of Visit*

Date	Location	User	Value	Reason
Oct-01-2020 16:52:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Oct/1/2020	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261017**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:09[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> <b>Symptom::</b>  FE VE R  <b>Were fever or systemic symptom NO s present on the last day the Subj ect Diary was completed?:</b>	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> FEVER	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> <b>Symptom::</b>  FAT IGU E  <b>Were fever or systemic symptom NO s present on the last day the Subj ect Diary was completed?:</b>	Initial Entry

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

2.b Symptom:

Date	Location	User	Value	Reason
Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> FATIGUE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> Symptom:: HEA DAC HE  Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> HEADACHE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> Symptom:: CH ILL S	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

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Subject Initials: ---

Generated By: (b) (4)

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			Were fever or systemic symptom NO s present on the last day the Subj ect Diary was completed?:	
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2.d Symptom:

Date	Location	User	Value	Reason
Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> CHILLS	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> Symptom:: VO MITI NG Were fever or systemic sympto ms present on the last day the S ubject Diary was completed?: NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> VOMITING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
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090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)



Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> <b>Symptom::</b>  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry  DIA RRH EA NO
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2.f Symptom:

Date	Location	User	Value	Reason
Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> DIARRHEA	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> <b>Symptom::</b>  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry  NEW OR WORSENE D MUSCL E PAIN NO

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261017**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:09**2.g Symptom:**

Date	Location	User	Value	Reason
Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NEW OR WORSENERD MUSCLE PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2.h**

Date	Location	User	Value	Reason
Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSENERD JOINT PAIN  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

**2.h Symptom:**

Date	Location	User	Value	Reason
Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NEW OR WORSENERD JOINT PAIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACVOPFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACVOPFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> Injection Site Reaction:: RED NES S  Were injection site reactions pre NO sent on the last day the Subject Diary was completed?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACVOPFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> REDNESS	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACVOPFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACVOPFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> Injection Site Reaction:: SWE LLIN G  Were injection site reactions pr NO esent on the last day the Subjec t Diary was completed?:	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> SWELLING	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> PAIN AT INJECTION SITE  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

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

Date	Location	User	Value	Reason
Oct-01-2020 16:53:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (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: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-01-2020 16:53:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-01-2020 16:53:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-01-2020 16:53:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-01-2020 16:53:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-01-2020 16:53:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Oct/1/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-01-2020 16:53:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BP28JN	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-01-2020 16:53:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> BP28JN	Initial Entry

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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: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

5.b

Date	Location	User	Value	Reason
Oct-01-2020 16:53:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> Sample ID: BPRW98	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-01-2020 16:53:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> BPRW98	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-01-2020 16:53:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> Sample ID: BLC38N	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-01-2020 16:53:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> BLC38N	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020 **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:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261017**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:09[Back to Form](#)**I. Date of Visit**

Date	Location	User	Value	Reason
Oct-21-2020 19:53:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-21-2020 19:53:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-21-2020 19:52:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Oct-21-2020 19:52:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Oct-21-2020 19:52:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/21/2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-21-2020 19:52:12 (UTC-08:00) Pacific 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 Oct/21/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261017**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:09[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Oct-21-2020 19:53:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/21/2020	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Oct-21-2020 19:53:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/20/2020	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Feb-17-2021 00:36:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-16-2021 12:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-16-2021 12:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Symptom Resolved:  Nov/20/2020	New Information
Feb-15-2021 03:17:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM Query: Please confirm the symptoms are still ongoing for this COVID illness. If all symptoms for this illness are resolved; please update the Last Symptoms Resolved Date else clarify.
Oct-21-2020 19:53:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.a**

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Oct-21-2020 19:53:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b> YES	Initial Entry
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4.a Symptoms:

Date	Location	User	Value	Reason
Oct-21-2020 19:53:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Oct-21-2020 19:53:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.b

Date	Location	User	Value	Reason
Oct-21-2020 19:53:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED COUGH <b>Symptom Present:</b> NO	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Oct-21-2020 19:53:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Oct-21-2020 19:53:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Oct-21-2020 19:53:02 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom</b> NEW OR INCREASED S	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

(US & Canada)		(b) (4), (b) (6)	s: HORTNESS OF BREATH Symptom NO Present:
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4.c Symptoms:

Date	Location	User	Value	Reason
Oct-21-2020 19:53:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Oct-21-2020 19:53:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Oct-21-2020 19:53:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms: CHILLS Symptom Present: NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Oct-21-2020 19:53:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Oct-21-2020 19:53:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Oct-21-2020 19:53:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms: NEW OR INCREASED MUSCLE PAIN	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

			Symptom P YES resent:	
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4.e Symptoms:

Date	Location	User	Value	Reason
Oct-21-2020 19:53:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED MUSCLE PAI N	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Oct-21-2020 19:53:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.f

Date	Location	User	Value	Reason
Oct-21-2020 19:53:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW LOSS OF TASTE OR SMELL <b>Symptom Pr</b> NO <b>esent:</b>	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Oct-21-2020 19:53:02 (UTC-08:00) Pacific 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
Oct-21-2020 19:53:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Oct-21-2020 19:53:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED SORE THROAT	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

			Symptom P NO resent:	
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4.g Symptoms:

Date	Location	User	Value	Reason
Oct-21-2020 19:53:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Oct-21-2020 19:53:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Oct-21-2020 19:53:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> DIARRHEA <b>Symptom Present:</b> NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Oct-21-2020 19:53:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Oct-21-2020 19:53:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Oct-21-2020 19:53:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITING <b>Symptom Present:</b> NO	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

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

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

**4.i Symptoms:**

Date	Location	User	Value	Reason
Oct-21-2020 19:53:02 (UTC-08:00) Pacific 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
Oct-21-2020 19:53:02 (UTC-08:00) Pacific 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  
Oct/21/2020

**Form:** MICROBIOLOGY SPECIMEN - Audit Trail

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

**Form Status:**

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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Date	Location	User	Value	Reason
Oct-21-2020 19:53:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Oct-21-2020 19:53:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/20/2020	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Oct-21-2020 19:53:30 (UTC-08:00) Pacific 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
Oct-21-2020 19:53:30 (UTC-08:00) Pacific 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
Oct-21-2020 19:53:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Oct-21-2020 19:53:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Oct-22-2020 12:49:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

**7. Test Result:**

Date	Location	User	Value	Reason
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090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/21/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

Oct-22-2020 12:49:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry
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**9. Trade Name Other, Specify:**

Date	Location	User	Value	Reason
Oct-22-2020 12:49:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CORONAVIR PAN-2019 NCOV, NAA, QL (KAISER CLIA LAB)	Initial Entry



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/21/2020**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:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261017**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:09[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-21-2020 19:53:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-21-2020 19:53:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-21-2020 19:54:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-21-2020 19:53:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-21-2020 19:53:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> YES Date of Collection:  Oct/21/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-21-2020 19:54:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Sample ID:</b> RW82931	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-21-2020 19:54:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> RW82931	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

**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:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-21-2020 19:54:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-21-2020 19:54:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-21-2020 19:54:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Oct-21-2020 19:54:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SEE SELF SWAB	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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*I.a*

Date	Location	User	Value	Reason
Oct-21-2020 19:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIALIST <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

*I.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Oct-21-2020 19:55:10 (UTC-08:00) Pacific 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
Oct-21-2020 19:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*I.b*

Date	Location	User	Value	Reason
Oct-21-2020 19:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENCY ROOM <b>Occurrence of Visits or Contacts:</b> YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261017**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:09***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-21-2020 19:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

***1.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Oct-21-2020 19:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Number of Visits or Contacts:</i>  1	Initial Entry

***1.c***

Date	Location	User	Value	Reason
Oct-21-2020 19:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN <b>Occurrence of Visits or Contacts:</b> YES <i>Number of Visits or Contacts:</i>  1	Initial Entry

***1.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-21-2020 19:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

***1.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Oct-21-2020 19:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Number of Visits or Contacts:</i>  1	Initial Entry

***1.d***

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Oct-21-2020 19:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> URGENT CARE <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry
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***1.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-21-2020 19:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> URGENT CARE	Initial Entry

***1.d Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Oct-21-2020 19:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.e***

Date	Location	User	Value	Reason
Oct-22-2020 12:50:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE CONSULTATION <b>Occurrence of Visits or Contacts:</b> YES <i>Number of Visits or Contacts:</i> 1	Changed Information
Oct-21-2020 19:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE CONSULTATION <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/21/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261017**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:09***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-21-2020 19:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> TELEPHONE CONSULTATION	Initial Entry

***1.e Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Oct-22-2020 12:50:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Number of Visits or Contacts:</i> 1	Changed Information
Oct-21-2020 19:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.f***

Date	Location	User	Value	Reason
Oct-21-2020 19:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTHE R <b>Occurrence of Visits or Cont NO</b> <b>acts:</b>	Initial Entry

***1.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Oct-21-2020 19:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

***1.f Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Oct-21-2020 19:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Oct-21-2020 19:55:10	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

(UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	NO
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090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

Form: RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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**1. What is the treatment Identifier?**

Date	Location	User	Value	Reason
Oct-21-2020 19:55:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Concomitant Non-drug Treatment Pre-specified:**

Date	Location	User	Value	Reason
Oct-21-2020 19:55:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Treatment:**

Date	Location	User	Value	Reason
Oct-21-2020 19:55:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Treatment:**

Date	Location	User	Value	Reason
Oct-21-2020 19:55:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Oct-21-2020 19:55:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**6. Ongoing?**

Date	Location	User	Value	Reason
Oct-21-2020 19:55:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/21/2020

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Oct-21-2020 19:54:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID-19 ILLNESS	Initial Entry

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

Date	Location	User	Value	Reason
Oct-21-2020 19:54:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Oct-21-2020 19:54:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/21/2020

**Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Oct-21-2020 19:54:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Subcategory of Clinical Event:**

Date	Location	User	Value	Reason
Oct-21-2020 19:54:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Was a diagnosis obtained?**

Date	Location	User	Value	Reason
Oct-21-2020 19:54:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Toxicity Grade:**

Date	Location	User	Value	Reason
Oct-21-2020 19:54:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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1. Lab Panel:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined Identifier Not Done : Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

5.a Sponsor ID:

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

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

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.a Test:**

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.a Result:**

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.a Not Done:**

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.a LNMT**

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> Not Done : e <b>Test::</b> Not Done e <b>Result::</b> Not Done e <b>Not Done::</b> Not Done e	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

			<b>Lab Normal Range:</b>	Not Done
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5.b Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> Not Done : <b>Test::</b> Not Done	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

			<b>Result::</b>	Not Done
			<b>Not Done::</b>	Not Done
			<b>Lab Normal Range:</b>	Not Done

5.c Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

(US & Canada)	(b) (4), (b) (6)	<b>Sponsor-Defined Identifier</b>	Not Done
		<b>Test::</b>	Not Done
		<b>Result::</b>	Not Done
		<b>Not Done::</b>	Not Done
		<b>Lab Normal Range:</b>	Not Done

5.d Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.e

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

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

**Site No:** 1126

**Subject No:** 11261017

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

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

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> Not Done : e <b>Test::</b> Not Done e <b>Result::</b> Not Done e <b>Not Done::</b> Not Done e <b>Lab Normal Range:</b> Not Done e	Initial Entry



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

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

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.e Test:**

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.e Result:**

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.e Not Done:**

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.e LNMT**

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.f**

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> Not Done : e <b>Test::</b> Not Done e <b>Result::</b> Not Done e <b>Not Done::</b> Not Done e	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

			<b>Lab Normal Range:</b>	Not Done
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5.f Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> Not Done : <b>Test::</b> Not Done	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

			<b>Result::</b>	Not Done
			<b>Not Done::</b>	Not Done
			<b>Lab Normal Range:</b>	Not Done

5.g Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Oct-21-2020 19:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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1. Lab Panel:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined Identifier Not Done : Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

5.a Sponsor ID:

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

			<b>Lab Normal Range:</b>	Not Done
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5.b Sponsor ID:

Date	Location	User	Value	Reason
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5.b Test:

Date	Location	User	Value	Reason
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5.b Result:

Date	Location	User	Value	Reason
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5.b Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
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090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

			<b>Result::</b>	Not Done
			<b>Not Done::</b>	Not Done
			<b>Lab Normal Range:</b>	Not Done

5.c Sponsor ID:

Date	Location	User	Value	Reason
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5.c Test:

Date	Location	User	Value	Reason
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5.c Result:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

(US & Canada)	(b) (4), (b) (6)	<b>Sponsor-Defined Identifier</b>	Not Done
		<b>Test::</b>	Not Done
		<b>Result::</b>	Not Done
		<b>Not Done::</b>	Not Done
		<b>Lab Normal Range:</b>	Not Done

5.d Sponsor ID:

Date	Location	User	Value	Reason
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5.d Test:

Date	Location	User	Value	Reason
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5.d Result:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.e

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> Not Done : e <b>Test::</b> Not Done e <b>Result::</b> Not Done e <b>Not Done::</b> Not Done e <b>Lab Normal Range:</b> Not Done e	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

5.e Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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5.e LNMT

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.f

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined Identifier Not Done : Test:: Not Done : Result:: Not Done : Not Done:: Not Done : e	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

			<b>Lab Normal Range:</b>	Not Done
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5.f Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> Not Done : <b>Test::</b> Not Done	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

			<b>Result::</b>	Not Done
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			<b>Lab Normal Range:</b>	Not Done

5.g Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

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Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

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Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

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Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.h

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

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

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Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

(US & Canada)	(b) (4), (b) (6)	<b>Sponsor-Defined Identifier</b>	Not Done
		<b>:</b>	e
		<b>Test::</b>	Not Done
			e
		<b>Result::</b>	Not Done
			e
		<b>Not Done::</b>	Not Done
			e
		<b>Lab Normal Range:</b>	Not Done
			e

5.h Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

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090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1126

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**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> Not Done : e <b>Test::</b> Not Done e <b>Result::</b> Not Done e <b>Not Done::</b> Not Done e <b>Lab Normal Range:</b> Not Done e	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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5.i Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.j

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined Identifier Not Done : Test:: Not Done : Result:: Not Done : e	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

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

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

			<b>Not Done::</b>	Not Done
			<b>Lab Normal Range:</b>	Not Done

**5.j Sponsor ID:**

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.j Test:**

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.j Result:**

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.j Not Done:**

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.j LNMT**

Date	Location	User	Value	Reason
Oct-21-2020 19:55:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/21/2020

**Form:** VITAL SIGNS - COVID - Audit Trail

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

**Form Status:**

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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Date	Location	User	Value	Reason
Oct-21-2020 19:56:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

Form: VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Date:**

Date	Location	User	Value	Reason
Oct-21-2020 19:56:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/20/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Oct-21-2020 19:56:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Systolic::</b> 14 1 <b>Diastolic::</b> 92 <b>Respiratory Rate in respirations/ minute:</b> 18 <b>Heart Rate in beats/minute:</b> 99	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Oct-21-2020 19:56:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Systolic:**

Date	Location	User	Value	Reason
Oct-23-2020 00:32:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-22-2020 12:47:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	DATA CORRECT, SIGNIFICANCE UNKNOWN
Oct-21-2020 19:56:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 141 is outside of Normal Range 90 - 140.
Oct-21-2020 19:56:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 141	Initial Entry

**2.a Diastolic:**

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

Form: VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

Date	Location	User	Value	Reason
Oct-23-2020 00:32:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-22-2020 12:48:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	DATA CORRECT, SIGNIFICANCE UNKNOWN
Oct-21-2020 19:56:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Diastolic BP 92 is outside of Normal Range 60 - 90.
Oct-21-2020 19:56:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 92	Initial Entry

**2.a Respiratory Rate in respirations/minute:**

Date	Location	User	Value	Reason
Oct-21-2020 19:56:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 18	Initial Entry

**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Oct-21-2020 19:56:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 99	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/21/2020

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

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

**Form Status:**

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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Date	Location	User	Value	Reason
Oct-21-2020 19:56:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Date:**

Date	Location	User	Value	Reason
Oct-21-2020 19:56:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/20/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Oct-21-2020 19:56:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:: 1</b> <b>Oxygen Saturation: 100.0</b>	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Oct-21-2020 19:56:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a SPO2 Pulse Oximetry %**

Date	Location	User	Value	Reason
Oct-21-2020 19:56:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 100.0	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/21/2020

**Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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**1. Date Time of Assessment:**

Date	Location	User	Value	Reason
Oct-21-2020 19:57:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Arterial Blood Gases PaO2 (mmHg):**

Date	Location	User	Value	Reason
Oct-21-2020 19:57:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. FiO2 (Fraction of Inhaled Oxygen):**

Date	Location	User	Value	Reason
Oct-21-2020 19:57:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/21/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-21-2020 19:57:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-21-2020 19:57:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-21-2020 19:57:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Oct-21-2020 19:57:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Oct-21-2020 19:57:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Oct-21-2020 19:57:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Oct/21/2020

**Form:** IMAGING - eCRF Audit Trail History

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Oct-21-2020 19:57:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Location of Assessment:**

Date	Location	User	Value	Reason
Oct-21-2020 19:57:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Type of Imaging Exam:**

Date	Location	User	Value	Reason
Oct-21-2020 19:57:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Assessment:**

Date	Location	User	Value	Reason
Oct-21-2020 19:57:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled Visit  
on Nov/24/2020

**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:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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**1. Date of Visit**

Date	Location	User	Value	Reason
Nov-25-2020 15:12:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/24/2020	Initial Entry

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

Date	Location	User	Value	Reason
Nov-25-2020 15:12:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COVID_A1	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_CONVA 1 - Unscheduled Visit on Nov/24/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Nov-25-2020 15:13:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-25-2020 15:13:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-27-2020 12:21:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_03
Nov-27-2020 09:16:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-27-2020 09:16:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/24/2020	Transcription Error
Nov-25-2020 18:32:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6245566;Date of Collection is not equal to Date of Visit. Please clarify or correct.
Nov-25-2020 15:13:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_CONVA 1 - Unscheduled Visit on Nov/24/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

			Nov/25/2020	
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5.a

Date	Location	User	Value	Reason
Nov-25-2020 15:12:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPZZ04	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-25-2020 15:12:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPZZ04	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-27-2020 09:24:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BLC38G	Transcription Error
Nov-25-2020 15:13:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BLC386	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_CONVA 1 - Unscheduled Visit on Nov/24/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

5.b Sample ID

Date	Location	User	Value	Reason
Nov-27-2020 12:22:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_06
Nov-27-2020 09:24:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-27-2020 09:24:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLC38G	Transcription Error
Nov-25-2020 22:48:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6245593;The barcode BLC386 is recorded for two subjects 11261017 and 11261216, please review and update as appropriate.
Nov-25-2020 15:13:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLC386	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-27-2020 09:25:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BLC3HW	Transcription Error
Nov-25-2020 15:13:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BLC3HN	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled Visit on Nov/24/2020

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

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

**5.c Sample ID**

Date	Location	User	Value	Reason
Nov-27-2020 12:22:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_06
Nov-27-2020 09:25:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-27-2020 09:25:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLC3HW	Transcription Error
Nov-25-2020 22:48:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6245594;The barcode BLC3HN is recorded for two subjects 11261017 and 11261217, please review and update as appropriate.
Nov-25-2020 15:13:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLC3HN	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Nov/24/2020

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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**I. Date of Visit**

Date	Location	User	Value	Reason
Nov-26-2020 00:32:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query is invalid or does not apply
Nov-25-2020 15:11:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Nov-25-2020 15:11:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/24/2020	Initial Entry

**2. Erroneous Visit**

Date	Location	User	Value	Reason
Nov-25-2020 15:11:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ERRONEOUS VISIT	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Oct-01-2020 16:54:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Oct/1/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-01-2020 16:54:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-01-2020 16:54:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

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Date	Location	User	Value	Reason
Sep-01-2020 16:25:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Date	Location	User	Value	Reason
Jan-07-2021 15:49:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

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Date	Location	User	Value	Reason
Jan-12-2021 14:02:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Date	Location	User	Value	Reason
Jan-12-2021 14:03:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	Form Created	

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Date	Location	User	Value	Reason
Jan-12-2021 14:04:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Date	Location	User	Value	Reason
Jan-12-2021 14:05:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	Form Created	

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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Date	Location	User	Value	Reason
Jan-29-2021 13:12:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Category:**

Date	Location	User	Value	Reason
Sep-01-2020 16:25:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-01-2020 16:25:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Sep-01-2020 16:25:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Acute sinusitis	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Sep-01-2020 16:25:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/15/2020 04:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Sep-01-2020 16:25:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Aug/20/2020 12:00	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Sep-01-2020 16:25:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7. Is the adverse event serious?**

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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
Sep-01-2020 16:25:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Sep-01-2020 16:25:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-01-2020 16:25:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment(s), th is event is due to:  OTHER  If Other, specify:  UNKNOWN	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-01-2020 16:25:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-01-2020 16:25:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

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**Site No:** 1126

**Subject No:** 11261017

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

Date	Location	User	Value	Reason
Sep-01-2020 16:25:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Sep-01-2020 16:25:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Sep-01-2020 16:25:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

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Site No: 1126

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Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Category:**

Date	Location	User	Value	Reason
Jan-07-2021 15:49:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Jan-07-2021 15:49:27 (UTC-08:00) Pacific 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-02-2021 12:27:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Closed	Response satisfies query
Mar-02-2021 08:12:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (6)	Query 2: Answered	Data changed to satisfy query
Feb-28-2021 22:50:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (6) (b) (6)	Query 2: Opened	CLINQUERY: Per query responses at vax 4, the subject did not receive vax 4 due to events post vax 3. Please review responses to question 'action taken with study treatment' since no AE is marked as DRUG WITHDRAWN
Feb-26-2021 10:36:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Candidate	CLINQUERY: Per query responses at vax 4, the subject did not receive vax 4 due to events post vax 3. Please review responses to question 'action taken with study treatment' since no AE is marked as DRUG WITHDRAWN

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

Jan-21-2021 08:40:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Carlos Linn (b) (4)	Query 1: Closed	Response satisfies query
Jan-18-2021 20:39:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The vaccine allergic reaction occurred during the vaccine transition option dose #1 of Pfizer BioNTech vaccine, vaccination #4, V101
Jan-18-2021 01:04:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Carlos Linn (b) (4)	Query 1: Reissued:Opened	Response does not satisfy query
Jan-08-2021 13:43:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-08-2021 13:43:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VACCINE ALLERGIC REACTION	Transcription Error
Jan-08-2021 11:46:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Carlos Linn (b) (4)	Query 1: Opened	Please clarify the vaccine allergic reaction? or specify the IP-related AE dated on 07/JAN/2021? (The VAX 2 was on 21/SEP2020, and placebo). Did the vaccine allergic reaction refer to the "outside" study vaccine (non-IP treatment)?
Jan-07-2021 15:49:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VACCINE ALLERGIC REACTINO	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Jan-07-2021 15:49:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/7/2021 11:37	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Jan-11-2021 16:41:58 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	New Information

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Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Generated Time (GMT): 29-Mar-2021 11:09

(US & Canada)		(b) (4), (b) (6)	End Date Time: Jan/8/2021 UNK:UNK	
Jan-07-2021 15:49:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-07-2021 15:49:27 (UTC-08:00) Pacific 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
Jan-07-2021 15:49:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Jan-07-2021 15:49:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-07-2021 15:49:27 (UTC-08:00) Pacific 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
Mar-09-2021 00:06:24 (UTC-08:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

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Header Text: c4591001

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Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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Pacific Time (US & Canada)				
Mar-08-2021 10:53:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please clarify query = AE marked Drug Withdrawn to satisfy query
Mar-07-2021 22:53:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	The Adverse Event Action Taken is DRUG WITHDRAWN but reason for treatment discontinuation is not reported as ADVERSE EVENT or DEATH. Please review and clarify. (b) (4)
Mar-02-2021 08:12:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DRUG WITHDRAWN	Data changed to satisfy query
Jan-07-2021 15:49:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

II. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-07-2021 15:49:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-07-2021 15:49:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

13. What was the outcome of this adverse event?:

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**Visit:** Logs - Unscheduled

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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Date	Location	User	Value	Reason
Jan-11-2021 21:12:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-11-2021 16:42:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Jan-11-2021 16:42:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry
Jan-07-2021 23:15:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Please complete this item. Thank you.

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Jan-07-2021 15:49:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Category:**

Date	Location	User	Value	Reason
Jan-12-2021 14:02:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Jan-12-2021 14:02:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Jan-12-2021 14:02:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Facial Flushing	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Jan-12-2021 14:02:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Jan/7/2021 11:37	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Jan-12-2021 14:02:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO End Date Time: Jan/8/2021 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Jan-12-2021 14:02:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> 2	Initial Entry

**7. Is the adverse event serious?**

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Jan-12-2021 14:02:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> 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
Jan-12-2021 14:02:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-12-2021 14:02:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-12-2021 14:02:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-12-2021 14:02:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-12-2021 14:02:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Jan-12-2021 14:02:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<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
Jan-12-2021 14:02:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1126**Subject No:** 11261017**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:09[Back to Form](#)**1. Category:**

Date	Location	User	Value	Reason
Jan-12-2021 14:03:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Jan-12-2021 14:03:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

**3. Adverse Event:***(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Jan-19-2021 05:15:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-18-2021 20:39:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	1) No dermal fillers used EVER 2) Swelling was entire face
Jan-15-2021 05:36:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: pls advise if swelling was entire face or localized to specific areas and whether subject has a hx of use of dermal fillers. Thanks
Jan-12-2021 14:03:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Facial swelling	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Jan-12-2021 14:03:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Jan/7/2021 11:37	Initial Entry

**5. Is the adverse event still ongoing?**

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

Date	Location	User	Value	Reason
Jan-12-2021 14:03:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO End Date Time:  Jan/8/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-12-2021 14:03:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<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
Jan-12-2021 14:03:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<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
Jan-12-2021 14:03:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-12-2021 14:03:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-12-2021 14:03:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Jan-12-2021 14:03:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Jan-12-2021 14:03:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> YES	Initial Entry

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Jan-12-2021 14:03:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Jan-12-2021 14:03:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

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**1. Category:**

Date	Location	User	Value	Reason
Jan-12-2021 14:04:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Jan-12-2021 14:04:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Jan-12-2021 14:04:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Hives, abdomen	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Jan-12-2021 14:04:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Jan/7/2021 14:50	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Jan-12-2021 14:04:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO End Date Time: Jan/8/2021 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Jan-12-2021 14:04:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> 1	Initial Entry

**7. Is the adverse event serious?**

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Jan-12-2021 14:04:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<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
Jan-12-2021 14:04:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-12-2021 14:04:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-12-2021 14:04:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-12-2021 14:04:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-12-2021 14:04:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> YES	Initial Entry

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**Site No:** 1126

**Subject No:** 11261017

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Jan-12-2021 14:04:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<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
Jan-12-2021 14:04:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

Header Text: c4591001

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Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

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**1. Category:**

Date	Location	User	Value	Reason
Jan-12-2021 14:05:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Jan-12-2021 14:05:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Jan-12-2021 14:05:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Nausea	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Jan-12-2021 14:05:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Jan/7/2021 12:50	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Jan-12-2021 14:05:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO End Date Time: Jan/7/2021 14:00	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Jan-12-2021 14:05:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> 1	Initial Entry

**7. Is the adverse event serious?**

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Header Text: c4591001

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Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Jan-12-2021 14:05:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> 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
Jan-12-2021 14:05:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-12-2021 14:05:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-12-2021 14:05:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-12-2021 14:05:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-12-2021 14:05:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> YES	Initial Entry

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**Subject No:** 11261017

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**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Jan-12-2021 14:05:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<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
Jan-12-2021 14:05:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

Header Text: c4591001

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Subject No: 11261017

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Category:**

Date	Location	User	Value	Reason
Jan-29-2021 13:12:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Jan-29-2021 13:12:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Jan-29-2021 13:12:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Muscle aches	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Jan-29-2021 13:12:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Jan/8/2021 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Jan-29-2021 13:12:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO End Date Time: Jan/9/2021 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Jan-29-2021 13:12:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> 1	Initial Entry

**7. Is the adverse event serious?**

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Jan-29-2021 13:12:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> 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
Jan-29-2021 13:12:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-29-2021 13:12:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-29-2021 13:12:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-29-2021 13:12:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-29-2021 13:12:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Jan-29-2021 13:12:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<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
Jan-29-2021 13:12:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:**

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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Date	Location	User	Value	Reason
Oct-01-2020 16:54:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	Form Created	

**Header Text:** c4591001  
**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1126  
**Subject No:** 11261017  
**Generated By:** (b) (4)

**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site Name:** (1126) Kaiser Permanente Santa Clara  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 11:09

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Oct-01-2020 16:54:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Oct-01-2020 16:54:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATIONS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Oct-01-2020 16:54:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry

**4. Medication:**

*Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).*

Date	Location	User	Value	Reason
Oct-01-2020 16:54:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Influenza vaccine (Fluarix quadrivalent)	Initial Entry

**5. Date:**

Date	Location	User	Value	Reason
Oct-01-2020 16:54:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Sep/21/2020	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - Unscheduled    **Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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*I. Date of Visit*

Date	Location	User	Value	Reason
Dec-27-2020 21:40:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Dec/21/2020	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:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

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*1. Select appropriate response - Is participant willing to return for Vaccination 3?*

Date	Location	User	Value	Reason
Dec-27-2020 21:40:29 (UTC-08:00) Pacific 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

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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*I. Date of Visit*

Date	Location	User	Value	Reason
Jan-08-2021 13:07:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Jan/7/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** INFORMED CONSENT - FURTHER VACCINATION - eCRF Audit Trail History

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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**I. Consent Was:**

Date	Location	User	Value	Reason
Jan-08-2021 13:07:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Jan/7/2021	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF  
Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Jan-08-2021 13:07:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Jan/7/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Jan-08-2021 13:07:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Jan-08-2021 13:07:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-08-2021 13:08:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Jan-08-2021 13:08:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Jan-08-2021 13:08:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Jan/7/2021	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Jan-08-2021 13:08:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Jan-08-2021 13:08:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Jan-08-2021 13:08:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Defined 113 <b>Identifier:</b> Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1126

**Subject No:** 11261017

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

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

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Jan-08-2021 13:08:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Jan-08-2021 13:08:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Jan-08-2021 13:08:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (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:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261017**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:09[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-08-2021 13:08:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-08-2021 13:08:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-08-2021 13:08:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-08-2021 13:08:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-08-2021 13:08:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Jan/7/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-08-2021 13:08:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BPZZ7S	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-08-2021 13:08:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> BPZZ7S	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: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

5.b

Date	Location	User	Value	Reason
Jan-08-2021 13:08:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> Sample ID: BS7VKR	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-08-2021 13:08:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> BS7VKR	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-08-2021 13:08:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> Sample ID: BLC3LV	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-08-2021 13:08:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<u>Data Entry:</u> BLC3LV	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (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:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261017**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:09[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-08-2021 13:09:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-08-2021 13:09:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-08-2021 13:09:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-08-2021 13:09:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-08-2021 13:09:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Jan/7/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-08-2021 13:09:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BP294K	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-08-2021 13:09:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> BP294K	Initial Entry

Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Jan-08-2021 13:09:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jan-08-2021 13:09:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jan-08-2021 13:09:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Jan-08-2021 13:09:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Jan/7/2021 11:32	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jan-08-2021 13:09:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Jan-08-2021 13:09:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
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090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

Jan-08-2021 13:09:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry
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**8. Actual Dose:**

Date	Location	User	Value	Reason
Jan-08-2021 13:09:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Jan-08-2021 13:09:32 (UTC-08:00) Pacific 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-08-2021 13:09:32 (UTC-08:00) Pacific 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-08-2021 13:09:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Dec-27-2020 21:40:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/21/2020	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Dec-27-2020 21:40:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADDITI ONAL VACCINATION	Initial Entry

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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*I. Date of Visit*

Date	Location	User	Value	Reason
Jan-29-2021 12:38:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/28/2021	Initial Entry

**Header Text:** c4591001**Visit:** V102\_VAX4**Form Version:** 10-Dec-2020 02:23**Site No:** 1126**Subject No:** 11261017**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:09[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-29-2021 12:38:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Jan-29-2021 12:38:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Jan-29-2021 12:38:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Jan-29-2021 12:38:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Jan-29-2021 12:38:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Jan-29-2021 12:38:54 (UTC-08:00) Pacific 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	Initial Entry

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

			Not Done::	Not Applicable
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-29-2021 12:38:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-29-2021 12:38:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jan-29-2021 12:38:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Jan-29-2021 12:38:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (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: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-29-2021 12:40:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-29-2021 12:40:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-29-2021 12:40:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/28/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-29-2021 12:39:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR7YWY	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-29-2021 12:39:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR7YWY	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)



Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

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**I. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Feb-11-2021 22:39:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-11-2021 08:14:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Every possible box is marked NOT DONE to prove that it is NOT DONE
Feb-10-2021 10:41:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM RQ: Please enter a FORM LEVEL comment (located across from Form Title), scroll down and select Not Done so entire form can be updated. For further instruction see section 4.10 of the CRF Completion Requirements.
Feb-10-2021 08:37:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	All "Data" has been deleted - Everything is marked NOT DONE
Feb-09-2021 02:44:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Data has not been deleted as requested. Kindly remove all entered data using the eraser icon. Once all entered data has been removed, an option to tick Not Done becomes available at form level comment. Please update or clarify.
Feb-08-2021 17:35:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Data deleted per query
Feb-08-2021 00:16:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Please remove all entered data using the eraser icon. Once all entered data has been removed, an option to tick Not Done becomes

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

**Header Text:** c4591001  
**Visit:** V102\_VAX4  
**Form Version:** 10-Dec-2020 02:26  
**Site No:** 1126  
**Subject No:** 11261017  
**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History  
**Form Status:** Data Complete, Frozen, Verified  
**Site Name:** (1126) Kaiser Permanente Santa Clara  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 11:09

				available at form level comment. Please update or clarify.
Feb-05-2021 13:51:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please clarify query - previous query asked for the data to be marked NOT DONE
Feb-05-2021 00:01:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Please consider to add form level comment as "NOT APPLICABLE" on Vaccination form. Thank you.
Feb-04-2021 12:21:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Feb-04-2021 12:21:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Data changed to NOT DONE to satisfy query only
Feb-04-2021 12:21:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Data marked NOT DONE to satisfy query only
Feb-03-2021 22:02:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Please consider adding form level comment Not Done at 'Was there a temporary delay of vaccination?' as well. Thank you.
Feb-03-2021 15:51:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Already marked NOT DONE
Feb-03-2021 00:37:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Please consider adding form level comment Not done if vaccination is not given. Ask CRA in case any assistance if needed. Thank you.
Jan-29-2021 12:40:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

<b>2. Treatment Name</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

Feb-11-2021 08:13:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
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3. Formulation:

Date	Location	User	Value	Reason
Feb-11-2021 08:13:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Mar-02-2021 12:30:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Closed	AE and EOT2 updated
Feb-26-2021 10:16:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Please clarify query - AE Allergic Reaction already entered, EOT matches V103
Feb-26-2021 09:02:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Opened	CLINQUERY: Comment applied in query response suggests Vax 4 was not given due to reactions post Vax 3. However, no AE entries indicate DRUG WITHDRAWN. Please review AEs and confirm which should be updated to match; EOT2 should reflect same
Feb-02-2021 18:31:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_EC001_2_14
Feb-02-2021 14:59:22 (UTC-08:00) Pacific Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

& Canada)				
Feb-02-2021 14:57:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please clarify query - the data is NA not NOT DONE
Feb-02-2021 05:51:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Per query response provided, kindly consider to add a form level comment NOT DONE at this form.
Feb-01-2021 14:05:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	See comment "Subject did not get vaccinated. Due to meeting Exclusion Criteria # 3"
Feb-01-2021 03:03:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7063007;Dose Date is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Jan-29-2021 12:42:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-11-2021 08:13:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Feb-02-2021 14:59:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Jan-29-2021 12:40:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1126

Subject No: 11261017

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1126) Kaiser Permanente Santa Clara

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:09

7. Route:

Date	Location	User	Value	Reason
Feb-11-2021 08:13:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-11-2021 08:13:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-11-2021 08:13:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-11-2021 08:13:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

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

Date	Location	User	Value	Reason
Feb-08-2021 17:35:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Feb-08-2021 17:35:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Data deleted per query
Jan-29-2021 12:40:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO <i>If No, specify reason:</i>  Subject did not get vaccinated. Due to meeting Exclusion Criteria # 3.	Initial Entry

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**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-25-2021 16:03:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Feb/25/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** CONTACT OUTCOME - eCRF Audit Trail History

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

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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**1. Contact Type:**

Date	Location	User	Value	Reason
Feb-25-2021 16:03:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Feb-25-2021 16:03:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> YES Date of Contact:  Feb/25/2021	Initial Entry

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**Header Text:** c4591001**Visit:** FURTHER\_VACCINATION\_EOT -  
Unscheduled**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Version:** 20-Feb-2021 02:26**Form Status:** Data Complete, Frozen, Verified**Site No:** 1126**Site Name:** (1126) Kaiser Permanente Santa Clara**Subject No:** 11261017**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:09[Back to Form](#)**I. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Mar-04-2021 06:51:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Closed	Response satisfies query
Mar-03-2021 16:40:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Mar-03-2021 16:40:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/28/2021	Changed Information
Mar-02-2021 12:28:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 2: Opened	CLINQUERY: Please review the date added to this end of treatment page. At V102/Vax4 it appears a decision was made to discontinue Rx (not administer Vax 4). This visit is prior to the date entered here
Mar-01-2021 21:40:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Date matches with V103.
Mar-01-2021 13:51:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please clarify query - Per protocol and DEG this data is captured at V103
Feb-26-2021 16:54:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7479488;Status on the Disposition - Treatment form is COMPLETED, but Date is different than Visit 3 Date. Please



Header Text: c4591001

Visit: FURTHER\_VACCINATION\_EOT -  
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

				review and update as appropriate.
Feb-25-2021 16:04:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry:</b> Feb/25/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-25-2021 16:04:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> OPEN LABEL TREATMENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-04-2021 06:51:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Clo sed	Response satisfies query
Mar-03-2021 16:40:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Changed Information
Mar-03-2021 16:40:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : ADV ERSE EVEN T	Changed Information
Mar-02-2021 12:26:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Rei ssued: Opene d	CLINQUERY: The allergic reaction post Vax 3 is logged in the AE listing with DRUG WITHDRAWN status now. Please update EOT2 page to match (status ADVERSE EVENT) if this AE was what led to withholding Vax 4
Mar-02-2021 11:40:36	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Clo	site confirms data correct as is

090177e196ae3d4e\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: FURTHER\_VACCINATION\_EOT -  
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1126

Site Name: (1126) Kaiser Permanente Santa Clara

Subject No: 11261017

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:09

(UTC-08:00) Pacific Time (US & Canada)			sed	
Mar-02-2021 08:12:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Ans wered	Per previous AE2 marked DRUG WITHDRAWN
Mar-02-2021 05:04:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Rei ssued: Opene d	DM1: Thanks for your response. Status on the Disposition - Treatment form is COMPLETED at FURTHER_VACCINATION_EOT visits but at least one Dose Date is missing. Please verify status and update as appropriate.
Mar-01-2021 13:56:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	Subject did not get vaccinated. Due to meeting Exclusion Criteria # 3.
Mar-01-2021 13:56:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Ans wered	Subject did not get vaccinated. Due to meeting Exclusion Criteria # 3.
Mar-01-2021 03:35:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Op ened	DMW7479181;Status on the Disposition - Treatment form is COMPLETED at FURTHER_VACCINATION_EOT visits but at least one Dose Date is missing. Please review and update as appropriate.
Feb-27-2021 12:13:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Rei ssued: Opene d	CLINQUERY: End of Treatment (EOT) status should reflect the reason for treatment discontinuation at vax 4. Please review why vax 4 was not administered and match status selection
Feb-26-2021 15:05:07	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans	According to Protocol and DEG EOT2 is completed when V103 is

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**Header Text:** c4591001

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

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:09

(UTC-08:00) Pacific Time (US & Canada)			were	completed, as is the case here.
Feb-26-2021 12:43:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Reissued: Opened	CLINQUERY: Both doses need to have been received within the treatment phase for status COMPLETED to be applied. Per Vax 4 pg, subject did not receive that dose due to symptoms/events post Vax 3. Please match date and status of EOT to this info
Feb-26-2021 10:11:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please clarify query - Per Protocol and DEG data is entered at V103
Feb-26-2021 08:59:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Status COMPLETED is entered but Vax 4 was not administered. Please select status based on reason for not dosing at Vax4 and dated when decision to not dose was made.
Feb-25-2021 16:04:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Charlie Chao (b) (4)	<b>Data Entry</b> : COMPLETED	Initial Entry

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**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1126

**Subject No:** 11261017

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

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:09

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**1. Subject Status**

Date	Location	User	Value	Reason
Oct-01-2020 16:54:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-13-2020 14:06:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-13-2020 13:58:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Oct-01-2020 16:54:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/1/2020	Initial Entry
Aug-13-2020 14:06:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/13/2020	Initial Entry
Aug-13-2020 13:58:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/13/2020	Initial Entry

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**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

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

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

**Site No:** 1126

**Site Name:** (1126) Kaiser Permanente Santa Clara

**Subject No:** 11261017

**Subject Initials:** ---

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

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*I. Casebook Signature*

Date	Location	User	Value	Reason
Sep-10-2020 15:53:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Click Here to Enable	Initial Entry