

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/11/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[12651101]
2.	Birth Date:	(b) (6)/1973
3.	Sex:	FEMALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Form Comments

Inclusion Criteria Not Met

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

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Sep/11/2020
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: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

eCRF Audit Trail History

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Syncope and collapse]
	Start Date:	Oct/7/2005
	Ongoing:	NO End Date: UNK/UNK/2005
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Sinus tachycardia]
	Start Date:	Jun/5/2007
	Ongoing:	NO End Date: UNK/UNK/2007
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Single seizure, unspecified type]
	Start Date:	Jun/5/2007
	Ongoing:	NO End Date: Jun/5/2007
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Major depressive disorder, recurrent episode]
	Start Date:	Jan/25/2007
	Ongoing:	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Irritable bowel syndrome]
	Start Date:	Jun/17/2004
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Gastroesophageal reflux disease]
	Start Date:	Apr/10/2006
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Generalized anxiety disorder]
	Start Date:	Feb/28/2008
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Overactive bladder]
	Start Date:	Aug/6/2010
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Fibromyalgia]
	Start Date:	Nov/2/2007
	Ongoing:	YES

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Fatty liver]
	Start Date:	Oct/18/2006
	Ongoing:	YES
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Diabetes mellitus, type 2]
	Start Date:	May/26/2011
	Ongoing:	YES
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Bipolar 1 disorder, mixed, moderate]
	Start Date:	Jan/26/2010
	Ongoing:	YES
1.m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Chronic abdominal pain]
	Start Date:	Aug/17/2006
	Ongoing:	YES
1.n	Line/MH Number:	[14]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Chronic kidney disease, stage 2]
	Start Date:	Feb/11/2014
	Ongoing:	YES

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

1.o	Line/MH Number:	[15]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Dyslipidemia]
	Start Date:	Jun/27/2013
	Ongoing:	YES
1.p	Line/MH Number:	[16]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Gastroparesis]
	Start Date:	Dec/31/2014
	Ongoing:	YES
1.q	Line/MH Number:	[17]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Peripheral neuropathy]
	Start Date:	May/3/2013
	Ongoing:	YES
1.r	Line/MH Number:	[18]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	Jan/19/2017
	Ongoing:	YES
1.s	Line/MH Number:	[19]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Asthma]
	Start Date:	Aug/16/2016
	Ongoing:	YES

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

1.t	Line/MH Number:	[20]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Benign fasciculation cramp syndrome]
	Start Date:	Aug/30/2013
	Ongoing:	YES
1.u	Line/MH Number:	[21]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Chronic pancreatitis]
	Start Date:	Jan/19/2017
	Ongoing:	YES
1.v	Line/MH Number:	[22]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Obesity]
	Start Date:	Apr/13/2011
	Ongoing:	YES
1.w	Line/MH Number:	[23]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Right blepharospasm]
	Start Date:	Oct/9/2014
	Ongoing:	YES
1.x	Line/MH Number:	[24]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Colonoscopy with biopsy]
	Start Date:	Nov/15/2010
	Ongoing:	NO End Date: Nov/15/2010

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

1.y	Line/MH Number:	[25]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Colonoscopy with biopsy]
	Start Date:	Jul/8/2014
	Ongoing:	NO End Date: Jul/8/2014
1.z	Line/MH Number:	[26]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Fallopian tube ligation]
	Start Date:	UNK/UNK/1998
	Ongoing:	NO End Date: UNK/UNK/1998
1.aa	Line/MH Number:	[27]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Laparoscopic hysterectomy]
	Start Date:	Dec/12/2013
	Ongoing:	NO End Date: Dec/12/2013
1.ab	Line/MH Number:	[28]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Laparoscopic lysis of intra-abdominal adhesion]
	Start Date:	May/15/2015
	Ongoing:	NO End Date: May/15/2015

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

1.ac	Line/MH Number:	[29]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Laparoscopic salpingectomy (bilateral)]
	Start Date:	Dec/12/2013
	Ongoing:	NO End Date: Dec/12/2013
1.ad	Line/MH Number:	[30]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Diagnostic laparoscopy]
	Start Date:	May/15/2015
	Ongoing:	NO End Date: May/15/2015
1.ae	Line/MH Number:	[31]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Drug allergy - Nexium [Esomeprazole Magnesium]]
	Start Date:	Jan/17/2008
	Ongoing:	YES

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/11/2020
2.	Weight:	[81.0]
3.	Unit:	kg
4.	Height:	[149.9]
5.	Unit:	cm
6.	Body Mass Index:	[36.0]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[37.0]
	Unit:	C
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/11/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Sep/11/2020
2.	Randomization Number:	[88271]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP956J]
5.b	Sample ID	[BP956K]
5.c	Sample ID	[BP956L]
5.d	Sample ID	[BMNCC1]
5.e	Sample ID	[BMNCC2]

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP950Y]
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/11/2020 12:02
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Vital Signs

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

2.a	Record Identifier:	1
	Temperature:	[36.5]
	Unit:	C
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/30/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/30/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPY4BL]
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/30/2020 11:53
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (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: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/6/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/11/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Date of Visit differs from Date of Collection because the participant was a No Show for their lab appointment scheduled for 11/06/20. The lab appointment was rescheduled to and completed on 11/11/20.]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR9YZ2]
5.b	Sample ID	[BMNN2F]
5.c	Sample ID	[BMNN2G]

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/02/2020 **Form:** DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Date of Visit

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

COVID-19 Illness Visit

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

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/02/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Nov/2/2020
2.	Date of First Symptom Started:	Oct/27/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Nov/6/2020

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	YES
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	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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090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/02/2020 **Form:** MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Nov/2/2020
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:	[CLIA certified laboratory]

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/02/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[CV01558]
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090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/02/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[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:	[Telephone visit was conducted; subject did not come on site for nasal swab.]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/02/2020 **Form:** HEALTH CARE UTILIZATION

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Health Care Utilization

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	NO
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	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:	[]
----	-------------------------------------	-----

Health Care Utilization

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

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/02/2020 **Form:** RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Respiratory Treatment

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/02/2020 **Form:** ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[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: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/02/2020 **Form:** ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Illness Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/02/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Not Started

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Lab Chemistry Details

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

Lab Result

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

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/02/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Laboratory Data Hematology

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

Lab Result

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

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID
Nov/02/2020

Form Version: 21-Aug-2020 02:50

Form Status: Not Started

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Vital Signs

1.	Date:	//
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Vital Signs Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/02/2020 **Form:** VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/02/2020 **Form:** OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Oxygenation Parameters

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/02/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Concomitant Medications

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

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING
Nov/02/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Imaging

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020 **Form:** DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Date of Visit

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

COVID-19 Illness Visit

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

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Dec/11/2020
2.	Date of First Symptom Started:	Dec/10/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Dec/10/2020

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

Symptoms - Other

5.a	Symptoms - Other Text:	[Chest pain]
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090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.b

Symptoms - Other Text:

[Dizzyness]

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020 **Form:** MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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[Form Comments](#)

[eCRF Audit Trail History](#)

Microbiology Specimen

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

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Dec/17/2020
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	[RR08237]
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090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[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:	[Subject will collect nasal self-swab]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020 Form: HEALTH CARE UTILIZATION

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020 **Form:** RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Respiratory Treatment

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020 **Form:** ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[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 2

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020 **Form:** ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Illness Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Not Started

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Lab Chemistry Details

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

Lab Result

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

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Laboratory Data Hematology

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

Lab Result

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

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020 **Form:** VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Form Status: Not Started

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020 **Form:** VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020 **Form:** OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Oxygenation Parameters

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

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Concomitant Medications

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

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** IMAGING
Dec/11/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Imaging

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

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
on Nov/30/2020

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Date of Visit

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

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY on Nov/30/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/30/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR9Z0M]
-----	-----------	----------

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 2 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
on Jan/08/2021

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Date of Visit

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

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_B1
----	-------------------------	----------

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 2 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
on Jan/08/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/8/2021
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	[BS68N1]
5.b	Sample ID	[BS68N2]
5.c	Sample ID	[BR9Z04]

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Unplanned Assessments

1.	Assessments	
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Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Nov/6/2020
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: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Hypoglycemia	Sep/12/2020 UNK: UNK	NO End Date Time: Sep/13/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Confusion/altered mental status	Sep/28/2020 UNK: UNK	NO End Date Time: Sep/29/2020 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	Abdominal pain	Sep/25/2020 UNK: UNK	NO End Date Time: Oct/8/2020 UNK:UNK	Repeating Pages
4.	ADVERSE EVENT	4	Allergic reaction	Oct/30/2020 UNK: UNK	NO End Date Time: Nov/1/2020 UNK:UNK	Repeating Pages

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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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)	[Hypoglycemia]
4.	Start Date Time:	Sep/12/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/13/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES
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: CONCOMITANT DRUG TREATMENT
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020380079]

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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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)	[Confusion/altered mental status]
4.	Start Date Time:	Sep/28/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/29/2020 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:	NOT RELATED If Not Related to study treatment(s), this event is due to: CONCOMITANT DRUG TREATMENT
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

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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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)	[Abdominal pain]
4.	Start Date Time:	Sep/25/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/8/2020 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:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Suspected irritable bowel syndrome]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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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)	[Allergic reaction]
4.	Start Date Time:	Oct/30/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/1/2020 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:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [None]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

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Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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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	[]

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Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	Flulaval Quadrivalent	Oct/22/2020	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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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).	[Flulaval Quadrivalent]
5.	Date:	Oct/22/2020

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Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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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: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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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?	

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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?	

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Contact Outcome

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

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

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/27/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Withdrawal Of Consent

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

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/16/2021
----	--------------	--

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:30

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation /Death :	Feb/16/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:		
2.	Lab Sub-Panel:		
3.	Collection Date:	Not Done //	Comments
4.	Laboratory Name and Address (Derived)	[]	
5.	Specimen Type:		

Lab Result

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

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/16/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR9Z3B]
5.b	Sample ID	[BS68TK]
5.c	Sample ID	[BS68TL]

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/16/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR9YT4]
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Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[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:	Feb/16/2021 09:17
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

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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

Lab Urinalysis

1.	Lab Panel:	Not Done _____	Comments
2.	Lab Sub-Panel:	Not Done _____	Comments
3.	Collection Date:	Not Done _____ //	Comments
4.	Laboratory Name and Address (Derived)	Not Done _____ []	Comments
5.	Specimen Type:	Not Done _____	Comments

Lab Result

6.a	Sponsor ID:	Not Done _____ []	Comments
	Test:	Not Done _____ Choriogonadotropin Beta_PX113	
	Result:	Not Done _____	Comments
	Not Done:	Not Done _____	Comments

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Mar/8/2021
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	[BR9Z6T]
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Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[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:	Mar/8/2021 09:00
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

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Contact Outcome

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

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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: Not Started

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Disposition - Treatment

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Nov/6/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
William Towner	Approved	Mar-09-2021 20:07:57 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, WilliamTowner, 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: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-11-2020 14:25:35 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

Item	Date	User	Comment
Form	Dec-11-2020 12:53:53 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

Item	Date	User	Comment
1	Dec-11-2020 12:53:53 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [Redacted] [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

Item	Date	User	Comment
2	Dec-11-2020 12:53:53 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [Redacted] [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Item	Date	User	Comment
3	Dec-11-2020 12:53:53 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [Redacted] [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

Item	Date	User	Comment
4	Dec-11-2020 12:53:53 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [Redacted] [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

Item	Date	User	Comment
5	Dec-11-2020 12:53:53 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [Redacted] [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Item	Date	User	Comment
6	Dec-11-2020 12:53:53 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [Redacted] [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

Item	Date	User	Comment
7	Dec-11-2020 12:53:53 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [Redacted] [Redacted]	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Item	Date	User	Comment
8	Dec-11-2020 12:53:53 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Item	Date	User	Comment
9	Dec-11-2020 12:53:53 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [Redacted] [Redacted]	Not Done

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: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-16-2021 11:25:14 (UTC-08:00) Pacific Time (US & Canada)	Jasmine Lopez (b) (4)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

Item	Date	User	Comment
3	Feb-16-2021 11:26:52 (UTC-08:00) Pacific Time (US & Canada)	Jasmine Lopez (b) (4)	Patient is not a female of childbearing potential. Not Done

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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Item	Date	User	Comment
Form	Mar-08-2021 15:15:37 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Patient is not a female of childbearing potential. Not Done

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

Item	Date	User	Comment
1	Mar-08-2021 15:15:37 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Patient is not a female of childbearing potential. Not Done

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

Item	Date	User	Comment
2	Mar-08-2021 15:15:37 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Patient is not a female of childbearing potential. Not Done

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

Item	Date	User	Comment
3	Mar-08-2021 15:15:37 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Patient is not a female of childbearing potential. Not Done

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

Item	Date	User	Comment
4	Mar-08-2021 15:15:37 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Patient is not a female of childbearing potential. <hr/> Not Done

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

Item	Date	User	Comment
5	Mar-08-2021 15:15:37 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Patient is not a female of childbearing potential. Not Done

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

Item	Date	User	Comment
6.a	Mar-08-2021 15:15:37 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Patient is not a female of childbearing potential. <hr/> Not Done

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

Item	Date	User	Comment
6.a	Mar-08-2021 15:15:37 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Patient is not a female of childbearing potential. <hr/> Not Done

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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Item	Date	User	Comment
6.a	Mar-08-2021 15:15:37 (UTC-08:00) Pacific Time (US & Canada)	(b) (4), (b) (6)	Patient is not a female of childbearing potential.
			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: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
William Towner	Approved	Mar-09-2021 20:07:57 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, WilliamTowner, 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-27-2021 14:45:54 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

William Towner	Approved	Jan-22-2021 12:26:40 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, WilliamTowner, 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-21-2021 09:53:55 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

William Towner	Approved	Jan-20-2021 18:03:08 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (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: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Affidavit:

By my dated signature below, I, WilliamTowner, 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-24-2020 09:40:08 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

William Towner	Approved	Nov-16-2020 08:23:29 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, WilliamTowner, 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-13-2020 15:09:00 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

William Towner	Approved	Nov-11-2020 14:26:52 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, WilliamTowner, 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-11-2020 14:23:24 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (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: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Affidavit:

N/A

William Towner	Approved	Nov-11-2020 12:33:32 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, WilliamTowner, 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-10-2020 17:17:22 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

William Towner	Approved	Nov-10-2020 10:47:43 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, WilliamTowner, 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-02-2020 14:38:48 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

William Towner	Approved	Nov-02-2020 11:39:02 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
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090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Status: Data Complete, Signed, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Affidavit:

By my dated signature below, I, WilliamTowner, 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: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-11-2020 14:24:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 14:24:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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I. Consent Was:

Date	Location	User	Value	Reason
Sep-11-2020 14:24:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Sep/11/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Subject ID

Date	Location	User	Value	Reason
Sep-11-2020 14:24:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12651101	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:24:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1973	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-11-2020 14:25:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-11-2020 14:25:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HISPANIC OR LATINO(A) OR OF S PANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 14:25:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-11-2020 14:25:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/11/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-11-2020 14:25:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/11/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-11-2020 14:25:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-11-2020 14:25:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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I.a

Date	Location	User	Value	Reason
Sep-11-2020 14:26:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Syncope and collapse Start Date: Oct/7/2005 Ongoing: NO End Date: UNK/UNK/2005	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 14:26:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 14:26:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Syncope and collapse	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:26:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/7/2005	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 14:26:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2005	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

I.b

Date	Location	User	Value	Reason
Sep-11-2020 14:27:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Te rm: Sinus tachycardia Start Date: Jun/5/2007 Ongoing: NO End Date: UNK/UNK/2 007	Initial Entry

I.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 14:27:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 14:27:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sinus tachycardia	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:27:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jun/5/2007	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 14:27:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2007	Initial Entry

I.c

Date	Location	User	Value	Reason
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090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Sep-11-2020 14:27:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 3 ber: Medical Histor Single seizure, unsp y Term: epecified type Start Date: Jun/5/2007 Ongoing: NO End Date: Jun/5/2007	Initial Entry
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I.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 14:27:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 14:27:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Single seizure, unspecified type	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:27:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jun/5/2007	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 14:27:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Jun/5/2007	Initial Entry

I.d

Date	Location	User	Value	Reason
Sep-11-2020 14:28:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 4 mber:	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			Medical History Term: Major depressive disorder, recurrent episode Start Date: Jan/25/2007 Ongoing: YES
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I.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 14:28:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 14:28:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Major depressive disorder, recurrent episode	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:28:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/25/2007	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 14:28:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Sep-11-2020 14:28:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: Irritable bowel syndrome Start Date: Jun/17/2004 Ongoing: YES	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

I.e Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 14:28:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 14:28:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Irritable bowel syndrome	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:28:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jun/17/2004	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 14:28:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Sep-11-2020 14:28:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 6 ber: Medical Histor Gastroesophageal ref y Term: lux disease Start Date: Apr/10/2006 Ongoing: YES	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

I.f Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 14:28:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 6	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 14:28:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Gastroesophageal reflux disease	Initial Entry

I.f Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:28:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Apr/10/2006	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 14:28:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

I.g

Date	Location	User	Value	Reason
Sep-11-2020 14:29:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Number: Medical History Generalized anxiety Term: disorder Start Date: Feb/28/2008 Ongoing: YES	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

I.g Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 14:29:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 7	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 14:29:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Generalized anxiety disorder	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:29:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Feb/28/2008	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 14:29:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

I.h

Date	Location	User	Value	Reason
Sep-11-2020 14:29:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Number: 8 Medical History Term: Overactive bladder Start Date: Aug/6/2010 Ongoing: YES	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

I.h Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 14:29:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 14:29:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Overactive bladder	Initial Entry

I.h Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:29:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/6/2010	Initial Entry

I.h Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 14:29:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.i

Date	Location	User	Value	Reason
Sep-11-2020 14:30:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 9 Medical History Term: Fibromyalgia Start Date: Nov/2/2007 Ongoing: YES	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

I.i Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 14:30:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 14:30:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Fibromyalgia	Initial Entry

I.i Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:30:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/2/2007	Initial Entry

I.i Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 14:30:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.j

Date	Location	User	Value	Reason
Sep-11-2020 14:31:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 10 Medical History Term: Fatty liver Start Date: Oct/18/2006 Ongoing: YES	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Lj Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 14:31:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

Lj Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-11-2020 14:31:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Fatty liver	Initial Entry

Lj Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:31:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/18/2006	Initial Entry

Lj Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 14:31:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

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Subject Initials: ---

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1.k

Date	Location	User	Value	Reason
Sep-11-2020 14:32:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 11 r: Medical History Term: Diabetes mellitus, type 2 Start Date: May/26/2011 Ongoing: YES	Initial Entry

1.k Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 14:32:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 14:32:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Diabetes mellitus, type 2	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:32:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: May/26/2011	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 14:32:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.l

Date	Location	User	Value	Reason
Sep-11-2020 14:32:29 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 12	Initial Entry

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Header Text: c4591001

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Form Status: Data Complete, Frozen, Verified

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Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

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(US & Canada)			mber: Medical Histo Bipolar 1 disorder, mi ry Term: xed, moderate Start Date: Jan/26/2010 Ongoing: YES	
---------------	--	--	---	--

1.1 Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 14:32:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12	Initial Entry

1.1 Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-11-2020 14:32:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bipolar 1 disorder, mixed, moderate	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:32:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/26/2010	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 14:32:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.m

Date	Location	User	Value	Reason
Sep-11-2020 14:34:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numbe 13 r: Medical History Chronic abdomina Term: l pain Start Date: Aug/17/2006 Ongoing: YES	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

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1.m Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 14:34:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 13	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 14:34:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Chronic abdominal pain	Initial Entry

1.m Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:34:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/17/2006	Initial Entry

1.m Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 14:34:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.n

Date	Location	User	Value	Reason
Sep-11-2020 14:35:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 14 Medical History Term: Chronic kidney disease, stage 2 Start Date: Feb/11/2014 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Subject No: 12651101

Generated By: (b) (4)

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1.n Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 14:35:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 14	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 14:35:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Chronic kidney disease, stage 2	Initial Entry

1.n Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:35:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/11/2014	Initial Entry

1.n Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 14:35:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.o

Date	Location	User	Value	Reason
Sep-11-2020 14:36:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 15 Medical History Term: Dyslipidemia Start Date: Jun/27/2013 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Subject No: 12651101

Generated By: (b) (4)

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Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

I.o Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 14:36:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 15	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 14:36:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dyslipidemia	Initial Entry

I.o Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:36:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jun/27/2013	Initial Entry

I.o Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 14:36:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.p

Date	Location	User	Value	Reason
Sep-11-2020 14:36:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 16 Medical History Term: Gastroparesis Start Date: Dec/31/2014 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Subject No: 12651101

Generated By: (b) (4)

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Subject Initials: ---

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1.p Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 14:36:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 16	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 14:36:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Gastroparesis	Initial Entry

1.p Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:36:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/31/2014	Initial Entry

1.p Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 14:36:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.q

Date	Location	User	Value	Reason
Sep-11-2020 14:36:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 17 : Medical History Term: Peripheral neuropathy Start Date: May/3/2013 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Subject No: 12651101

Generated By: (b) (4)

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1.q Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 14:36:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 17	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 14:36:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Peripheral neuropathy	Initial Entry

1.q Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:36:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: May/3/2013	Initial Entry

1.q Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 14:36:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.r

Date	Location	User	Value	Reason
Sep-11-2020 14:37:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 18 Medical History Term: Hypertension Start Date: Jan/19/2017 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Generated By: (b) (4)

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I.r Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 14:37:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 18	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 14:37:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hypertension	Initial Entry

I.r Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:37:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/19/2017	Initial Entry

I.r Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 14:37:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.s

Date	Location	User	Value	Reason
Sep-11-2020 14:37:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 19 Medical History Term: Asthma Start Date: Aug/16/2016 Ongoing: YES	Initial Entry

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Subject Initials: ---

Generated By: (b) (4)

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I.s Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 14:37:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 19	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 14:37:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Asthma	Initial Entry

I.s Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:37:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/16/2016	Initial Entry

I.s Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 14:37:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.t

Date	Location	User	Value	Reason
Sep-11-2020 14:38:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 20 mber: Medical Histo Benign fasciculation c ry Term: ramp syndrome Start Date: Aug/30/2013 Ongoing: YES	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

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1.t Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 14:38:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 20	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 14:38:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Benign fasciculation cramp syndrome	Initial Entry

1.t Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:38:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/30/2013	Initial Entry

1.t Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 14:38:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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I.u

Date	Location	User	Value	Reason
Sep-11-2020 14:39:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 21 Medical History Term: Chronic pancreatitis Start Date: Jan/19/2017 Ongoing: YES	Initial Entry

I.u Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 14:39:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 21	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 14:39:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Chronic pancreatitis	Initial Entry

I.u Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:39:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/19/2017	Initial Entry

I.u Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 14:39:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.v

Date	Location	User	Value	Reason
Sep-11-2020 14:41:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 22 Medical History Term: Obesity	Initial Entry

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			Start Date:	Apr/13/2011
			Ongoing:	YES

I.v Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 14:41:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 22	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 14:41:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Obesity	Initial Entry

I.v Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:41:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Apr/13/2011	Initial Entry

I.v Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 14:41:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.w

Date	Location	User	Value	Reason
Sep-11-2020 14:41:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 23 Medical History Te Right blepharosp rm: asm Start Date: Oct/9/2014 Ongoing: YES	Initial Entry

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Header Text: c4591001

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I.w Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 14:41:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 23	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 14:41:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Right blepharospasm	Initial Entry

I.w Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:41:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/9/2014	Initial Entry

I.w Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 14:41:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.x

Date	Location	User	Value	Reason
Sep-11-2020 14:43:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 24 r: Medical History Term: Colonoscopy with biopsy Start Date: Nov/15/2010 Ongoing: NO End Date: Nov/15/2010	Initial Entry

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Header Text: c4591001

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Subject No: 12651101

Generated By: (b) (4)

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I.x Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 14:43:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 24	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 14:43:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Colonoscopy with biopsy	Initial Entry

I.x Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:43:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/15/2010	Initial Entry

I.x Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 14:43:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Nov/15/2010	Initial Entry

I.y

Date	Location	User	Value	Reason
Sep-11-2020 14:43:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numbe 25 r: Medical History Colonoscopy with Term: biopsy Start Date: Jul/8/2014 Ongoing: NO End Date: Jul/8/2014	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

I.y Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 14:43:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 25	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 14:43:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Colonoscopy with biopsy	Initial Entry

I.y Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:43:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jul/8/2014	Initial Entry

I.y Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 14:43:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Jul/8/2014	Initial Entry

I.z

Date	Location	User	Value	Reason
Sep-11-2020 14:46:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 26 : Medical History T Fallopian tube lig erm: ation Start Date: UNK/UNK/1998 Ongoing: NO End Date: UNK/UNK/19 98	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

1.z Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 14:46:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 26	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 14:46:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Fallopian tube ligation	Initial Entry

1.z Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:46:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/1998	Initial Entry

1.z Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 14:46:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/1998	Initial Entry

1.aa

Date	Location	User	Value	Reason
Sep-14-2020 09:13:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Numb 27 er: Medical History Term: Laparoscopic hysterectomy Start Date: Dec/12/2013 Ongoing: NO End Date: Dec/12/2013	Transcription Error
Sep-11-2020 14:47:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numb 27 er:	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

			Medical History Term: Laparoscopic hysterectomy	
			Start Date: Dec/12/2013	
			Ongoing: NO	
			End Date:	
			Dec/12/2013	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

1.aa Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 14:47:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 27	Initial Entry

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

Date	Location	User	Value	Reason
Sep-14-2020 10:40:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Sep-14-2020 09:13:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-14-2020 09:13:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Laparoscopic hysterectomy	Transcription Error
Sep-12-2020 11:42:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify LAPAROSCOPIC HYSTERECTOMY as follows...Should the spelling be LAPAROSCOPIC HYSTERECTOMY? If so, edit. Otherwise clarify. Thank you.
Sep-11-2020 14:47:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Laparoscopic hysterectomy	Initial Entry

1.aa Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:47:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/12/2013	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

1.aa Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 14:47:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Dec/12/2013	Initial Entry

1.ab

Date	Location	User	Value	Reason
Sep-11-2020 14:47:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 28 umber: Medical His Laparoscopic lysis of intr tory Term: a-abdominal adhesion Start Date: May/15/2015 Ongoing: NO End Date: May/15/2015	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

I.ab Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 14:47:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 28	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 14:47:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Laparoscopic lysis of intra-abdominal adhesion	Initial Entry

I.ab Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:47:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: May/15/2015	Initial Entry

I.ab Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 14:47:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: May/15/2015	Initial Entry

I.ac

Date	Location	User	Value	Reason
Sep-11-2020 14:48:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 29 mber: Medical Hist Laparoscopic salpingec ory Term: tomy (bilateral) Start Date: Dec/12/2013 Ongoing: NO End Date: Dec/12/2013	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

I.ac Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 14:48:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 29	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 14:48:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Laparoscopic salpingectomy (bilateral)	Initial Entry

I.ac Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:48:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/12/2013	Initial Entry

I.ac Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 14:48:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Dec/12/2013	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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<i>I.ad</i>				
Date	Location	User	Value	Reason
Sep-11-2020 14:48:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 30 r: Medical History Term: Diagnostic laparoscopy Start Date: May/15/2015 Ongoing: NO End Date: May/15/2015	Initial Entry
<i>I.ad Line/MH Number:</i>				
Date	Location	User	Value	Reason
Sep-11-2020 14:48:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30	Initial Entry
<i>I.ad Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:</i>				
Date	Location	User	Value	Reason
Sep-11-2020 14:48:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Diagnostic laparoscopy	Initial Entry
<i>I.ad Start Date:</i>				
Date	Location	User	Value	Reason
Sep-11-2020 14:48:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: May/15/2015	Initial Entry
<i>I.ad Ongoing:</i>				
Date	Location	User	Value	Reason
Sep-11-2020 14:48:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: May/15/2015	Initial Entry
<i>I.ae</i>				

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Sep-11-2020 15:23:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 31 umber: Medical Hi Drug allergy - Nexium [story Term: Esomeprazole Magnesium m] Start Date: Jan/17/2008 Ongoing: YES	Initial Entry

1.ae Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 15:23:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 31	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 15:23:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Drug allergy - Nexium [Esomeprazole Magnesium]	Initial Entry

1.ae Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 15:23:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/17/2008	Initial Entry

1.ae Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 15:23:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:50:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/11/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-11-2020 14:50:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 81.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-11-2020 14:50:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-11-2020 14:50:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 149.9	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-11-2020 14:50:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-11-2020 14:50:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 36.0	Initial Entry

7.a

Date	Location	User	Value	Reason
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090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Sep-11-2020 14:50:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 37.0 Temperature Unit: C Temperature Location: ORAL CAVITY	Initial Entry
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7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-11-2020 14:50:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-11-2020 14:50:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 37.0	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-11-2020 14:50:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-11-2020 14:50:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-11-2020 14:50:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-11-2020 14:50:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-11-2020 14:50:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/11/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-11-2020 14:50:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-11-2020 14:50:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-11-2020 14:50:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined 113 Identifier: Test:: Choriogonadotropin Beta_PX113 Result::	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

			Not Done::	NOT DONE	
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-11-2020 14:50:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-11-2020 14:50:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-11-2020 14:50:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Randomization Date :

Date	Location	User	Value	Reason
Sep-11-2020 14:51:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/11/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-11-2020 14:51:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 88271	Initial Entry

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1265**Site Name:** (1265) Kaiser Permanente**Subject No:** 12651101**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-11-2020 14:51:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-11-2020 14:51:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-11-2020 16:56:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-11-2020 14:51:08 (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-11-2020 14:51:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/11/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-11-2020 16:56:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP956J	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-11-2020 16:56:16 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (6)	Data Entry: BP956J	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(US & Canada)		(b) (4)		
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5.b

Date	Location	User	Value	Reason
Sep-11-2020 16:56:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP956K	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-11-2020 16:56:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP956K	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-11-2020 16:56:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP956L	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-11-2020 16:56:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP956L	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-24-2020 09:40:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BMNCC1	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Nov-24-2020 09:40:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BMNCC1	Initial Entry

5.e

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090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (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, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Nov-24-2020 09:40:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BMNCC2	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Nov-24-2020 09:40:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BMNCC2	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:** 1265**Site Name:** (1265) Kaiser Permanente**Subject No:** 12651101**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-11-2020 14:51:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-11-2020 14:51:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-11-2020 16:57:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-11-2020 14:51:14 (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-11-2020 14:51:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/11/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-11-2020 16:57:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BP950Y	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-11-2020 16:57:22 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (6)	Data Entry: BP950Y	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: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(US & Canada)

(b) (4)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-11-2020 14:51:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-11-2020 14:51:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-11-2020 14:51:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-11-2020 14:51:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/11/2020 12:02	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-11-2020 14:51:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-11-2020 14:51:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Sep-11-2020 14:51:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-11-2020 14:51:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSE RVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-11-2020 14:51:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-11-2020 14:52:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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I. Date of Visit

Date	Location	User	Value	Reason
Oct-07-2020 03:33:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Per site confirmation- entered in error
Oct-06-2020 14:56:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	According to documentation from 9/18, it appears that this was done an accidental entry, as patient called regarding having issues with her daughter which led to her daughter taking her phone and mobile diary device.
Oct-06-2020 13:00:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	As per Illness edary records, subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 18SEP2020. But there is no COVID Illness visit reported in the database. Please clarify.
Sep-30-2020 13:43:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/30/2020	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date:

Date	Location	User	Value	Reason
Sep-30-2020 13:44:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/30/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-30-2020 13:44:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 36.5 Temperature Unit: C Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-30-2020 13:44:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-30-2020 13:44:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.5	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-30-2020 13:44:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-30-2020 13:44:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-30-2020 13:45:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-30-2020 13:45:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-30-2020 13:45:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/30/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-30-2020 13:45:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-30-2020 13:45:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-30-2020 13:45:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined 113 Identifier: Test:: Choriogonadotropin Beta_PX113 Result::	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			Not Done::	NOT DONE	
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-30-2020 13:45:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-30-2020 13:45:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-30-2020 13:45:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (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: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Data Origin

Date	Location	User	Value	Reason
Sep-30-2020 13:45:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-30-2020 13:45:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-01-2020 09:21:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-01-2020 02:04:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-30-2020 13:45:09 (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-30-2020 13:45:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/30/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-01-2020 09:21:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPY4BL	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (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: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.a Sample ID

Date	Location	User	Value	Reason
Oct-01-2020 09:21:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPY4BL	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-30-2020 13:48:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-30-2020 13:48:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-30-2020 13:48:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-30-2020 13:48:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/30/2020 11:53	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-30-2020 13:48:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-30-2020 13:48:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Sep-30-2020 13:48:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-30-2020 13:48:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSE RVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-30-2020 13:48:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Visit

Date	Location	User	Value	Reason
Nov-13-2020 20:38:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Clo sed	Response satisfies query
Nov-13-2020 15:07:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Ans wered	We were instructed to use date of first assessment (phone call) as V3 date and lab collection date as EOT date.
Nov-12-2020 05:06:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 3: Op ened	Blood draw happened on 11Nov2020, hence date of visit is expected to be the same date. Hence please consider updating the date of visit as applicable. Else clarify.
Nov-09-2020 21:36:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Clo sed	Response satisfies query
Nov-09-2020 17:27:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Ans wered	completed
Nov-09-2020 13:55:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Response satisfies query
Nov-09-2020 11:08:54 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	Subject unable to be contacted initially, causing subject to be out of window.

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(US & Canada)				
Nov-07-2020 03:47:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 2: Op ened	As per CRF guidelines, the treatment period is defined as 1st vaccination visit through the 1-month post vaccination visit after the 2nd vaccination. Please complete treatment disposition CRF and update date of EOT to match the date the Visit 3 blood draw
Nov-06-2020 23:56:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Op ened	PDQ: Date of visit at V3_MONTH1_POSTVAX2_L is out of window for 2 days from V2_VAX2_L DOV or V2 Vaccination date. Please verify and update. Else, confirm in query response appropriately. (b) (4)
Nov-06-2020 15:13:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Nov/6 /2020	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, Frozen, Verified**Site No:** 1265**Site Name:** (1265) Kaiser Permanente**Subject No:** 12651101**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-11-2020 14:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry
Nov-10-2020 17:17:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Labs not yet collected. Cleared date for now.
Nov-06-2020 15:13:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-11-2020 14:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry
Nov-10-2020 17:17:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Labs not yet collected. Cleared date for now.
Nov-06-2020 15:13:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-22-2021 01:30:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Clos ed	Response satisfies query
Feb-19-2021 14:55:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Jasmine Lopez (b) (4)	Query 6: Ans wered	Changed data per query.
Feb-19-2021 14:40:58	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Reis sued:Opened	PDQ RQ3: Because the sample was not

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
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Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

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Generated By: (b) (4)

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(UTC-08:00) Pacific Time (US & Canada)				collected on the date of visit, a response in Item 2 (If no sample was collected or sample was not collected according to protocol, please provide reason') field. Please update.
Feb-19-2021 08:31:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Jasmine Lopez (b) (4)	Query 6: Answered	Data is correct. Barcodes entered.
Feb-19-2021 00:02:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Reissued: Opened	PDQ RQ2 :Thank you for the response, however no data updated please consider to record the response for ' If no sample was collected or sample was not collected according to protocol, please provide reason'. else clarify.
Feb-18-2021 10:14:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Jasmine Lopez (b) (4)	Query 6: Answered	Changed data per query
Feb-17-2021 20:49:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Reissued: Opened	PDQ RQ1 : Thank you for the response, however please consider to record the response for ' If no sample was collected or sample was not collected according to protocol, please provide reason'. else clarify.
Feb-17-2021 08:59:55	ACV0PFEINFP6000	(b) (6)	Query 6: Answered	Data is correct.

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Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(UTC-08:00) Pacific Time (US & Canada)		(b) (4)		
Feb-16-2021 23:39:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Opened	PDQ : Date of Collection is not equal to Date of Visit. Please clarify or correct.
Jan-06-2021 07:13:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Response satisfies query
Jan-05-2021 10:21:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	Changed data per query
Jan-05-2021 08:59:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Opened	HOLDS: For visit 3, the lab has received serum sample barcodes BMNN2F, BMNN2G. However, the barcodes are not reported for this subject. Please review and update as appropriate. Otherwise please clarify.
Nov-13-2020 22:02:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Nov-13-2020 22:02:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Nov-13-2020 18:26:48 (UTC-08:00) Pacific Time	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 4: Opened	DMW5380093;Date of Collection is not equal to Date of Visit. Please clarify

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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
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Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

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Generated By: (b) (4)

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(US & Canada)				or correct.
Nov-13-2020 15:09:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Nov-13-2020 15:07:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	We were instructed to use date of first assessment (phone call) as V3 date and lab collection date as EOT date.
Nov-11-2020 19:00:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Opened	DMW5361172;Date of Collection is not equal to Date of Visit. Please clarify or correct.
Nov-11-2020 17:41:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-11-2020 14:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-11-2020 14:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/11/2020	Initial Entry
Nov-10-2020 17:17:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-10-2020 17:17:22 (UTC-08:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Labs not yet collected. Cleared date for now.

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Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
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Subject Initials: ---

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Pacific Time (US & Canada)				
Nov-06-2020 23:42:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-06-2020 15:13:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-06-2020 15:13:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/6/2020	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Feb-23-2021 12:00:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Jasmine Lopez (b) (4)	Data Entry: Date of Visit differs from Date of Collection because the participant was a No Show for their lab appointment scheduled for 11/06/20. The lab appointment was rescheduled to and completed on 11/11/20.	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-13-2020 15:09:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR9YZ2	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-13-2020 15:09:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR9YZ2	Initial Entry

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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

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5.b

Date	Location	User	Value	Reason
Jan-05-2021 10:20:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BMNN2F	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-05-2021 10:20:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BMNN2F	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-05-2021 10:21:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BMNN2G	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Jan-05-2021 10:21:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BMNN2G	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/02/2020 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: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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I. Date of Visit

Date	Location	User	Value	Reason
Nov-07-2020 01:15:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Nov-06-2020 15:55:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Changed data per query
Nov-06-2020 03:29:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM: Kindly review and complete 'Microbiology Specimen form' at this visit. Thank you.
Nov-04-2020 17:07:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-03-2020 07:16:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Nov-02-2020 14:51:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Nov-02-2020 14:50:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Nov-02-2020 14:50:36 (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

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/02/2020 **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: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

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				appropriate.
Nov-02-2020 14:50:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/2/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Nov-02-2020 14:50:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/02/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

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1. Date of Assessment:

Date	Location	User	Value	Reason
Nov-02-2020 14:51:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/2/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Nov-02-2020 14:51:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/27/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Dec-17-2020 00:15:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-16-2020 12:16:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Nov/6/2020	Spoke with subject to obtain date of symptom resolution.
Dec-16-2020 11:52:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Error - Need to assess date of symptom resolution with subject.
Dec-16-2020 11:46:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Dec-16-2020 11:46:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Oct/30/2020	Changed Information
Dec-14-2020 10:05:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	A COVID_B Visit was created with Symptoms starting 10DEC. New Illness visits should not be

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/02/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1265**Site Name:** (1265) Kaiser Permanente**Subject No:** 12651101**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51

				initiated if a current illness visit has ongoing symptoms. If COVID_A symptoms were ongoing; move all data from COVID_B into COVID_A and clear COVID_B forms with NA
Dec-10-2020 06:08:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-09-2020 15:45:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Symptoms ongoing as of last contact with subject.
Dec-08-2020 06:50:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Please clarify whether the reported symptoms are still ongoing? If symptoms have ended, please update 'Symptoms Ongoing' on to 'NO' and add Date of Last Symptom Resolved on the CRF.
Nov-02-2020 14:51:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Nov-02-2020 14:51:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Nov-02-2020 14:51:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/02/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

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Site No: 1265

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Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Nov-02-2020 14:51:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Nov-02-2020 14:51:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASE D COUGH Symptom Pr YES esent:	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Nov-02-2020 14:51:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Nov-02-2020 14:51:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Nov-02-2020 14:51:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREASED S s: HORTNESS OF BREATH Symptom NO Present:	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/02/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

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4.c Symptoms:

Date	Location	User	Value	Reason
Nov-02-2020 14:51:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Nov-02-2020 14:51:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Nov-02-2020 14:51:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Nov-02-2020 14:51:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Nov-02-2020 14:51:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Nov-02-2020 14:51:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom P YES resent:	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/02/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1265**Site Name:** (1265) Kaiser Permanente**Subject No:** 12651101**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51**4.e Symptoms:**

Date	Location	User	Value	Reason
Nov-02-2020 14:51:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MUSCLE PA IN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Nov-02-2020 14:51:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.f

Date	Location	User	Value	Reason
Nov-02-2020 14:51:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW LOSS OF TASTE OR SMELL Symptom P NO resent:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Nov-02-2020 14:51:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Nov-02-2020 14:51:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Nov-02-2020 14:51:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SORE THROAT Symptom P NO resent:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/02/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

4.g Symptoms:

Date	Location	User	Value	Reason
Nov-02-2020 14:51:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SORE THRO AT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Nov-02-2020 14:51:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Nov-02-2020 14:51:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Nov-02-2020 14:51:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Nov-02-2020 14:51:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Nov-02-2020 14:51:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITING Symptom Present: NO	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/02/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

4.i Symptoms:

Date	Location	User	Value	Reason
Nov-02-2020 14:51:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Nov-02-2020 14:51:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/02/2020 **Form:** MICROBIOLOGY SPECIMEN - Audit Trail

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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Date	Location	User	Value	Reason
Nov-06-2020 15:55:41 (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 Nov/02/2020 Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Nov-06-2020 15:55:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/2/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Nov-06-2020 15:55:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWABBED MATERIAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Nov-06-2020 15:55:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Nov-06-2020 15:55:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Nov-06-2020 15:55:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Nov-06-2020 15:55:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
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090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/02/2020 **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Nov-06-2020 15:55:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry
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9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Nov-06-2020 15:55:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CLIA certified laboratory	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/02/2020

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: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Data Origin

Date	Location	User	Value	Reason
Nov-04-2020 17:07:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-04-2020 17:07:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-16-2020 11:52:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Dec-16-2020 11:46:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Date of Collection is more than 4 days after Date of Last Symptom Resolved on the Signs and Symptoms form in the same visit. Please review and update as appropriate.
Nov-04-2020 17:07:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-04-2020 17:07:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-04-2020 17:07:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/4/2020	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/02/2020

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: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.a

Date	Location	User	Value	Reason
Nov-04-2020 17:07:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: CV01558	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-04-2020 17:07:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CV01558	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/02/2020**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:** 1265**Site Name:** (1265) Kaiser Permanente**Subject No:** 12651101**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-02-2020 14:54:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-02-2020 14:54:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-04-2020 21:44:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-04-2020 17:16:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Self swab has been collected and data entered.
Nov-03-2020 08:37:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Per CCG either Nasal SWAB Self or Nasal SWAB is expected to be collected. Kindly verify & update the data as appropriate; else clarify. Thanks
Nov-02-2020 14:54:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Nov-02-2020 14:54:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Telephone visit was conducted; subject did not come on site for nasal swab.	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/02/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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I.a

Date	Location	User	Value	Reason
Nov-02-2020 14:58:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: C NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-02-2020 14:58:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-02-2020 14:58:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Nov-02-2020 14:58:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/02/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1265**Site Name:** (1265) Kaiser Permanente**Subject No:** 12651101**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51***I.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-02-2020 14:58:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-02-2020 14:58:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.c

Date	Location	User	Value	Reason
Nov-02-2020 14:58:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-02-2020 14:58:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-02-2020 14:58:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

I.d

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/02/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Nov-02-2020 14:58:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry
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I.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-02-2020 14:58:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

I.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-02-2020 14:58:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.e

Date	Location	User	Value	Reason
Nov-02-2020 14:58:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/02/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1265**Site Name:** (1265) Kaiser Permanente**Subject No:** 12651101**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51***I.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-02-2020 14:58:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-02-2020 14:58:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

I.f

Date	Location	User	Value	Reason
Nov-02-2020 14:58:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTHE R Occurrence of Visits or Cont NO acts:	Initial Entry

I.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-02-2020 14:58:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

I.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-02-2020 14:58:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Has the subject been hospitalized due to potential COVID-19 illness?

Date	Location	User	Value	Reason
Nov-02-2020 14:58:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/02/2020 **Form:** ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Nov-02-2020 14:58:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Nov-02-2020 14:58:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-02-2020 14:58:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020 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: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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I. Date of Visit

Date	Location	User	Value	Reason
Dec-17-2020 20:58:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-17-2020 16:54:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query
Dec-14-2020 22:07:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Data is still missing in Nasal Swab Self form. Please complete.
Dec-14-2020 09:59:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject needed new self swab kit shipped to her house. She will plan to collect today, 12/14/2020.
Dec-14-2020 03:41:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Dec-11-2020 12:53:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Dec-11-2020 12:51:27 (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.
Dec-11-2020 12:51:27 (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

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020 **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: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

				review and update as appropriate.
Dec-11-2020 12:51:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/11/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Dec-11-2020 12:51:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_B	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Assessment:

Date	Location	User	Value	Reason
Dec-11-2020 12:53:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/11/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Dec-11-2020 12:53:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/10/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Feb-23-2021 14:19:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Dec/10/2020	New Information
Jan-15-2021 05:57:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-14-2021 15:51:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Per last visit with subject, symptoms were ongoing at that time.
Jan-14-2021 08:42:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Please clarify whether the reported symptoms are still ongoing? If symptoms have ended, please update 'Symptoms Ongoing' on to 'NO' and add Date of Last Symptom Resolved on the CRF.
Dec-18-2020 16:25:35 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (6)	Data Entry: YES	New Information

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(US & Canada)		(b) (4), (b) (6)		
Dec-11-2020 12:53:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Dec/10/2020	Initial Entry

4.a

Date	Location	User	Value	Reason
Dec-11-2020 12:53:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: YES	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Dec-11-2020 12:53:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Dec-11-2020 12:53:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.b

Date	Location	User	Value	Reason
Dec-11-2020 12:53:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASE D COUGH Symptom Present: NO	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete, Frozen**Site No:** 1265**Site Name:** (1265) Kaiser Permanente**Subject No:** 12651101**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51**4.b Symptoms:**

Date	Location	User	Value	Reason
Dec-11-2020 12:53:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Dec-11-2020 12:53:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Dec-11-2020 12:53:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREASED s: SHORTNESS OF BREA TH Symptom YES Present:	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Dec-11-2020 12:53:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHORTNES S OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Dec-11-2020 12:53:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.d

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete, Frozen**Site No:** 1265**Site Name:** (1265) Kaiser Permanente**Subject No:** 12651101**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51

Dec-11-2020 12:53:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry
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4.d Symptoms:

Date	Location	User	Value	Reason
Dec-11-2020 12:53:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Dec-11-2020 12:53:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Dec-11-2020 12:53:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom Present: NO	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Dec-11-2020 12:53:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MUSCLE P AIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Dec-11-2020 12:53:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

4.f

Date	Location	User	Value	Reason
Dec-11-2020 12:53:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW LOSS OF TASTE OR SMELL Symptom Present: NO	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Dec-11-2020 12:53:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Dec-11-2020 12:53:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Dec-11-2020 12:53:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SORE THROAT Symptom Present: NO	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

4.g Symptoms:

Date	Location	User	Value	Reason
Dec-11-2020 12:53:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Dec-11-2020 12:53:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Dec-11-2020 12:53:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Dec-11-2020 12:53:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Dec-11-2020 12:53:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Dec-11-2020 12:53:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (6)	<u>Data Entry:</u> Symptoms: VOMITING Symptom Present: NO	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

		(b) (4)		
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4.i Symptoms:

Date	Location	User	Value	Reason
Dec-11-2020 12:53:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Dec-11-2020 12:53:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-11-2020 12:53:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms - Other: Chest pain	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Dec-11-2020 12:53:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Chest pain	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-11-2020 12:53:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms - Other: Dizziness	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Dec-11-2020 12:53:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Dizziness	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020 Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Dec-11-2020 12:53:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Dec-11-2020 12:53:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Dec-11-2020 12:53:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Dec-11-2020 12:53:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Dec-11-2020 12:53:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
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090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020 **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Dec-11-2020 12:53:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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7. Test Result:

Date	Location	User	Value	Reason
Dec-11-2020 12:53:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Dec-11-2020 12:53:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Dec-11-2020 12:53:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020

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: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Data Origin

Date	Location	User	Value	Reason
Dec-17-2020 16:54:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-17-2020 16:54:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-24-2021 20:45:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-24-2021 13:36:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Jasmine Lopez (b) (4)	Query 3: Answered	Subject did not have a self-swab kit available at home on 12/11/20. A kit was shipped via UPS CampusShip. Subject was contacted and informed to collect self-swab on Monday, 12/14/2020. Subject collected their self-swab on 12/17/2020 per requisition card.
Feb-23-2021 14:19:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Date of Collection is more than 4 days after Date of Last Symptom Resolved on the Signs and Symptoms form in the same visit. Please review and update as appropriate.
Dec-18-2020 16:25:35 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020

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: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(US & Canada)				
Dec-17-2020 16:55:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-17-2020 16:54:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Date of Collection is more than 4 days after Date of Last Symptom Resolved on the Signs and Symptoms form in the same visit. Please review and update as appropriate.
Dec-17-2020 16:54:38 (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.
Dec-17-2020 16:54:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-17-2020 16:55:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: RR08237	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-17-2020 16:55:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RR08237	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020

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: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Data Origin

Date	Location	User	Value	Reason
Dec-11-2020 12:54:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-11-2020 12:54:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-11-2020 12:54:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Dec-11-2020 12:54:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Subject will collect nasal self-swab	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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I.a

Date	Location	User	Value	Reason
Dec-11-2020 12:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIAL IST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-11-2020 12:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-11-2020 12:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Dec-11-2020 12:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: EMERGENCY R OOM Occurrence of Vi sits or Contacts: YES <i>Number of Visit s or Contacts:</i> 1	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-11-2020 12:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-11-2020 12:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

1.c

Date	Location	User	Value	Reason
Dec-11-2020 12:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-11-2020 12:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-11-2020 12:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Dec-11-2020 12:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry
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1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-11-2020 12:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-11-2020 12:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Dec-11-2020 12:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-11-2020 12:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-11-2020 12:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

I.f

Date	Location	User	Value	Reason
Dec-11-2020 12:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTHE R Occurrence of Visits or Co ntacts: NO	Initial Entry

I.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-11-2020 12:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

I.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Dec-11-2020 12:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Has the subject been hospitalized due to potential COVID-19 illness?

Date	Location	User	Value	Reason
Dec-11-2020 12:55:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Dec/11/2020 Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Dec-11-2020 12:55:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Dec-11-2020 12:55:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-11-2020 12:55:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail on Nov/30/2020 History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Visit

Date	Location	User	Value	Reason
Nov-30-2020 16:26:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/30/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Nov-30-2020 16:27:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_A1	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled Visit
on Nov/30/2020**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1265**Site Name:** (1265) Kaiser Permanente**Subject No:** 12651101**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-30-2020 16:27:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-30-2020 16:27:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-30-2020 16:27:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-30-2020 16:27:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-30-2020 16:27:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/30/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-30-2020 16:27:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR9Z0M	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-30-2020 16:27:24 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (6)	Data Entry: BR9Z0M	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit
on Nov/30/2020

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(US & Canada)

(b) (4)

Header Text: c4591001

Visit: POT_COVID_CONVA 2 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail on Jan/08/2021
History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-12-2021 16:20:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/8/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Jan-12-2021 16:20:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_B1	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 2 - Unscheduled Visit on Jan/08/2021

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Data Origin

Date	Location	User	Value	Reason
Jan-12-2021 16:20:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-12-2021 16:20:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-22-2021 09:06:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-21-2021 09:54:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Barcode now entered.
Jan-21-2021 08:22:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	HOLDS: For Convalescent B visit the lab has received serum barcode BR9Z04; however, this barcode is not recorded. Please review and update as appropriate. Otherwise please clarify.
Jan-12-2021 16:20:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-12-2021 16:20:40 (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.

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 2 - Unscheduled Visit on Jan/08/2021

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Jan-12-2021 16:20:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/8/2021	Initial Entry
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5.a

Date	Location	User	Value	Reason
Jan-12-2021 16:21:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS68N1	Changed Information
Jan-12-2021 16:20:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS68S6	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-12-2021 16:21:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS68N1	Changed Information
Jan-12-2021 16:20:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS68S6	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-12-2021 16:22:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BS68N2	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-12-2021 16:22:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BS68N2	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-21-2021 09:53:55 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (6)	Data Entry: Sample ID: BR9Z04	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 2 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Jan/08/2021 Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(US & Canada)		(b) (4)	
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5.c Sample ID

Date	Location	User	Value	Reason
Jan-21-2021 09:53:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR9Z04	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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I. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-02-2021 21:05:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Closed	Auto closed by Validation Check: VC_DS001_21
Mar-02-2021 14:43:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/6/2020	New Information
Mar-02-2021 14:43:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	New Information
Mar-02-2021 14:43:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/7/2020	New Information
Mar-02-2021 05:29:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Opened	DMW7565918;Status on the Disposition - Treatment form is COMPLETED, but Date is different than Visit 3 Date. Please review and update as appropriate.
Mar-02-2021 02:50:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Data updated
Mar-01-2021 16:48:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Mar-01-2021 16:48:40	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/11/2020	New Information

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (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, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(UTC-08:00) Pacific Time (US & Canada)				
Feb-28-2021 08:43:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Saumitra Dubey (b) (4)	Query 2: Opened	P21 Review: End of treatment date is updated as 06Nov2020, but it should be same as blood drawn date on V3POSTVX2L visit which is 11Nov2020. Please check and correct the data, else clarify.
Nov-13-2020 22:01:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Closed	Date is equal to visit 3 blood draw. This is correct.
Nov-13-2020 22:01:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: lab collection date is 11Nov2020, but date reported here is 06Nov2020. Kindly verify and update.
Nov-13-2020 15:07:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	We were instructed to use date of first assessment (phone call) as V3 date and lab collection date as EOT date.
Nov-12-2020 05:07:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	As per CRF guidelines, the treatment period is defined as 1st vaccination visit through the 1-month post vaccination visit after the 2nd vaccination. Please complete treatment disposition CRF and update date of EOT to match the date the Visit 3 blood draw
Nov-09-2020 17:27:19 (UTC-08:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/6/2020	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (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, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Pacific Time
(US & Canada)

2. Phase of Disposition:

Date	Location	User	Value	Reason
Nov-09-2020 17:27:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Nov-09-2020 17:27:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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Date	Location	User	Value	Reason
Sep-30-2020 14:01:11 (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: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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Date	Location	User	Value	Reason
Sep-30-2020 15:15:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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Date	Location	User	Value	Reason
Oct-29-2020 15:56:04 (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: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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Date	Location	User	Value	Reason
Nov-02-2020 14:38:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Category:

Date	Location	User	Value	Reason
Sep-30-2020 14:01:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-30-2020 14:01:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-30-2020 18:52:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Sep-30-2020 17:16:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Sep-30-2020 17:16:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hypoglycemia	Changed Information
Sep-30-2020 17:11:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Multiple concepts in the term HYPOGLYCEMIA, ALTERED MENTAL STATUS SECONDARY TO ACUTE GRIEF. Split the term into HYPOGLYCEMIA, ALTERED MENTAL STATUS and ACUTE GRIEF

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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Subject Initials: ---

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				and submit separately. Thank you.
Sep-30-2020 14:59:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hypoglycemia, altered mental status secondary to acute grief	Changed Information
Sep-30-2020 14:01:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hypoglycemia, altered mental status acute grief	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-30-2020 14:01:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/12/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-30-2020 14:01:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/13/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-30-2020 14:59:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Changed Information
Sep-30-2020 14:01:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4	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).

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Date	Location	User	Value	Reason
Oct-01-2020 02:58:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-30-2020 17:51:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES	Transcription Error
Sep-30-2020 17:16:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Hypoglycemia: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-30-2020 15:00:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect?	Changed Information

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			<p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	
Sep-30-2020 14:59:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Hypoglycemia, altered mental status secondary to acute grief : Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-30-2020 14:01:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Hypoglycemia, altered mental status acute grief : Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-30-2020 14:01:11 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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Subject No: 12651101

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(US & Canada)			Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event NO	
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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-30-2020 14:01:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-02-2020 05:21:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-01-2020 08:23:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SAE Report form faxed to Safety 9/30/20 - event noted to be not related to study treatment on form.

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Header Text: c4591001

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Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Oct-01-2020 03:04:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020380079 ,causality was reported as NOT RELATED in AE CRF while recorded as NO DATA Safety database.Please confirm correct causality. If safety update is required, please submit a follow up form
Sep-30-2020 14:01:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment (s), this event is due to: CONCOMITANT DRUG TRE ATMENT	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-02-2020 05:18:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-01-2020 08:24:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Action taken with study treatment also marked as not applicable on SAE report form faxed to Safety on 9/30/20.
Oct-01-2020 03:03:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020380079 ,action taken was reported as NOT APPLICABLE in AE CRF while missing in Safety database.Please confirm correct action taken. If safety update is required, please submit a follow up form
Sep-30-2020 14:01:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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Site Name: (1265) Kaiser Permanente

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Subject Initials: ---

Generated By: (b) (4)

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Sep-30-2020 14:01:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-30-2020 14:01:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-02-2020 05:18:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-01-2020 08:24:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Event outcome noted as recovered/resolved on SAE report form faxed to Safety 9/30/20.
Oct-01-2020 03:01:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020380079,outcome was missing in Safety DB however, recorded as RECOVERED/RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Sep-30-2020 14:01:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Sep-30-2020 14:01:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-01-2020 02:58:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020380079	Initial Entry

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Subject No: 12651101

Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Sep-30-2020 15:15:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-30-2020 15:15:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-21-2020 20:32:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Thank you.
Oct-21-2020 17:04:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Information has been added to follow-up SAE form and will be submitted to Safety.
Oct-21-2020 08:23:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form to provide whether COVID testing was performed (yes/no) and if yes, the results. Thank you.
Sep-30-2020 15:15:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Confusion/altered mental status	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-30-2020 15:15:22 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (6)	Data Entry: Sep/28/2020 UNK:UNK	Initial Entry

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Site Name: (1265) Kaiser Permanente

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Subject Initials: ---

Generated By: (b) (4)

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(US & Canada)		(b) (4)	
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-30-2020 15:15:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/29/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-30-2020 15:15:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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
Sep-30-2020 15:15:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-30-2020 15:15:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-30-2020 15:15:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: CONCOMITANT DRUG TREAT	Initial Entry

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Generated By: (b) (4)

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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-30-2020 15:15:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-30-2020 15:15:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-30-2020 15:15:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Sep-30-2020 15:15:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Sep-30-2020 15:15:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Oct-29-2020 15:56:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-29-2020 15:56:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-29-2020 15:56:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Abdominal pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-29-2020 15:56:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/25/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-29-2020 15:56:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Oct/8/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-29-2020 15:56:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

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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
Oct-29-2020 15:56:04 (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
Oct-29-2020 15:56:04 (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
Oct-29-2020 15:56:04 (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), t his event is due to: OTHER If Other, specify: Suspected irritable bowel syndro me	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-29-2020 15:56:04 (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
Oct-29-2020 15:56:04 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	(b) (6)	<u>Data Entry:</u> YES	Initial Entry

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(US & Canada)

(b) (4)

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-29-2020 15:56:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-29-2020 15:56:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-29-2020 15:56:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Nov-02-2020 14:38:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-02-2020 14:38:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-02-2020 14:38:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Allergic reaction	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-02-2020 14:38:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/30/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-02-2020 14:38:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Nov/1/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-02-2020 14:38:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Nov-02-2020 14:38:48 (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
Nov-02-2020 14:38:48 (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
Nov-02-2020 14:38:48 (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), t his event is due to: OTHER If Other, specify: None	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-02-2020 14:38:48 (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
Nov-02-2020 14:38:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-02-2020 14:38:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Nov-02-2020 14:38:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-02-2020 14:38:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001
Visit: Logs - Unscheduled **Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Audit Trail
Form Version: 22-Apr-2020 21:03 **Form Status:**
Site No: 1265 **Site Name:** (1265) Kaiser Permanente
Subject No: 12651101 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

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Date	Location	User	Value	Reason
Nov-06-2020 15:14:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Nov-06-2020 15:14:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Nov-06-2020 15:14:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Nov-06-2020 15:14:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Nov-06-2020 15:14:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Flulaval Quadrivalent	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Nov-06-2020 15:14:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/22/2020	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (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: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-27-2021 14:45:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/27/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled **Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Jan-27-2021 14:46:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-27-2021 14:46:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-27-2021 14:46:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1 /2	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-27-2021 14:46:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/27/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-27-2021 14:46:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-16-2021 11:24:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Jasmine Lopez (b) (4)	Data Entry: Feb/16/2021	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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I. Consent Was:

Date	Location	User	Value	Reason
Feb-16-2021 11:24:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Jasmine Lopez (b) (4)	<u>Data Entry:</u> OBTAINED Date Written Consent Obtained Feb/16/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-16-2021 11:25:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Jasmine Lopez (b) (4)	Data Entry: Feb/16/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-16-2021 11:25:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-16-2021 11:25:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Jasmine Lopez (b) (4)	Data Entry: COMPLETED	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**Form Version:** 14-Jan-2021 02:21**Site No:** 1265**Subject No:** 12651101**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1265) Kaiser Permanente**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**3. Collection Date:**

Date	Location	User	Value	Reason
Feb-16-2021 11:26:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Jasmine Lopez (b) (4)	Data Entry: Not Done	Initial Entry

6.a

Date	Location	User	Value	Reason
Feb-16-2021 11:27:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE	Initial Entry
Feb-16-2021 11:26:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Jasmine Lopez (b) (4)	Data Entry: Sponsor-Defined Identifier: Test:: Choriogonadotropin Beta_PX113 Result:: Not Done::	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-16-2021 11:27:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Feb-16-2021 11:26:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Jasmine Lopez (b) (4)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Feb-16-2021 11:27:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Jasmine Lopez (b) (4)	Data Entry: NOT DONE	Initial Entry
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090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (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: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Data Origin

Date	Location	User	Value	Reason
Feb-16-2021 11:29:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-16-2021 11:29:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-16-2021 11:29:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-16-2021 11:29:02 (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.
Feb-16-2021 11:29:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Jasmine Lopez (b) (4)	Data Entry: YES Date of Collection: Feb/16/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-16-2021 11:29:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Jasmine Lopez (b) (4)	Data Entry: Sample ID: BR9Z3B	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-16-2021 11:29:23 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	Jasmine Lopez	Data Entry: BR9Z3B	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (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: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(US & Canada)		(b) (4)	
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5.b

Date	Location	User	Value	Reason
Feb-16-2021 11:29:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Jasmine Lopez (b) (4)	Data Entry: Sample ID: BS68TK	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-16-2021 11:29:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Jasmine Lopez (b) (4)	Data Entry: BS68TK	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-16-2021 11:29:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Jasmine Lopez (b) (4)	Data Entry: Sample ID: BS68TL	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-16-2021 11:29:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Jasmine Lopez (b) (4)	Data Entry: BS68TL	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (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:** 1265**Site Name:** (1265) Kaiser Permanente**Subject No:** 12651101**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-16-2021 11:30:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-16-2021 11:30:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-16-2021 11:30:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-16-2021 11:30:22 (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.
Feb-16-2021 11:30:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Jasmine Lopez (b) (4)	Data Entry: YES Date of Collection: Feb/16/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-16-2021 11:30:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Jasmine Lopez (b) (4)	Data Entry: Sample ID: BR9YT4	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-16-2021 11:30:41 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	Jasmine Lopez	Data Entry: BR9YT4	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(US & Canada)

(b) (4)

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-16-2021 11:31:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Jasmine Lopez (b) (4)	<u>Data Entry:</u> NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-16-2021 11:31:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-16-2021 11:31:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Feb-16-2021 11:31:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Jasmine Lopez (b) (4)	<u>Data Entry:</u> Feb/16/2021 09:17	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-16-2021 11:31:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Feb-16-2021 11:31:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Jasmine Lopez (b) (4)	<u>Data Entry:</u> LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Feb-16-2021 11:31:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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8. Actual Dose:

Date	Location	User	Value	Reason
Feb-16-2021 11:31:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-16-2021 11:31:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-16-2021 11:31:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-16-2021 11:31:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Jasmine Lopez (b) (4)	Data Entry: YES	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-08-2021 15:09:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/8/2021	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Lab Panel:

Date	Location	User	Value	Reason
Mar-08-2021 15:15:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Mar-08-2021 15:15:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Mar-08-2021 15:15:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Mar-08-2021 15:15:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Mar-08-2021 15:15:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

6.a

Date	Location	User	Value	Reason
Mar-08-2021 15:15:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done Test:: Not Done	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			Result::	Not Done
			Not Done::	Not Done

6.a Sponsor ID:

Date	Location	User	Value	Reason
Mar-08-2021 15:15:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Mar-08-2021 15:15:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Mar-08-2021 15:15:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Mar-08-2021 15:15:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (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: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Data Origin

Date	Location	User	Value	Reason
Mar-09-2021 08:55:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-09-2021 08:55:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-09-2021 08:55:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-09-2021 08:55:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-09-2021 08:55:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Jasmine Lopez (b) (4)	Data Entry: YES Date of Collection: Mar/8/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-09-2021 08:55:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Jasmine Lopez (b) (4)	Data Entry: Sample ID: BR9Z6T	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-09-2021 08:55:47 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	Jasmine Lopez	Data Entry: BR9Z6T	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (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: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

(US & Canada)

(b) (4)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Mar-08-2021 15:16:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Mar-08-2021 15:16:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Mar-08-2021 15:16:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Mar-08-2021 15:16:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/8/2021 09:00	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Mar-08-2021 15:16:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Mar-08-2021 15:16:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Mar-08-2021 15:16:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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8. Actual Dose:

Date	Location	User	Value	Reason
Mar-08-2021 15:16:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Mar-08-2021 15:16:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Mar-08-2021 15:16:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Mar-08-2021 15:16:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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1. Subject Status

Date	Location	User	Value	Reason
Nov-09-2020 17:27:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-11-2020 14:51:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-11-2020 14:25:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Mar-02-2021 14:43:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/6/2020	New Information
Mar-02-2021 14:43:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/7/2020	New Information
Mar-01-2021 16:48:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/11/2020	New Information
Dec-21-2020 21:48:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-21-2020 09:23:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Illness visit has been assessed and is considered a single illness visit, tied to previous COVID illness visit.
Dec-18-2020 05:56:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Illness ed diary: As per Illness ed diary records, subject reported "Yes" for the COVID-19 symptoms or diagnosis on 15DEC2020. But no corresponding COVID Illness visit

090177e196ae3036\Final\Final On: 01-Apr-2021 04:04 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1265

Subject No: 12651101

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1265) Kaiser Permanente

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

				indicate symptoms present at this date. Pls update Covid illness visit or clarify.
Nov-09-2020 17:27:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/6/2020	Initial Entry
Sep-11-2020 14:51:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/11/2020	Initial Entry
Sep-11-2020 14:25:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/11/2020	Initial Entry

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: 1265

Site Name: (1265) Kaiser Permanente

Subject No: 12651101

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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I. Casebook Signature

Date	Location	User	Value	Reason
Nov-02-2020 07:20:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	William Towner (b) (4)	Data Entry: Click Here to Enable	Initial Entry