

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

[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:** 1221

**Subject No:** 12211002

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

**Form:** MAIN INFORMED CONSENT

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[Form Comments](#)

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Oct/12/2020
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**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** DEMOGRAPHY

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[12211002]
2.	Birth Date:	(b) (6) 1977
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	AMERICAN INDIAN OR ALASKA NATIVE
6.	Racial Designation:	

**Header Text:** C4591001

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

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** DATE OF VISIT

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** C4591001

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

**Form Version:** 10-Oct-2020 16:00

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**Form Comments**

**Inclusion Criteria Not Met**

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

2.	Description of Exclusion Criterion Met	Not Applicable _____
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**Header Text:** C4591001

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

**Form Version:** 15-Sep-2020 21:52

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation/Death	Oct/13/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1221

Subject No: 12211002

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Coronary Stent placement]
	Start Date:	Jul/UNK/2019
	Ongoing:	NO End Date: Jul/UNK/2019
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Circumcision]
	Start Date:	Oct/UNK/2019
	Ongoing:	NO End Date: Oct/UNK/2020
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	Jul/15/2020
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Coronary Artery Disease]
	Start Date:	Jul/15/2020
	Ongoing:	YES

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypercholesterolemia]
	Start Date:	Jul/15/2020
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Diabetes Type 2]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[BPH]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Kidney Stones]
	Start Date:	UNK/UNK/2004
	Ongoing:	NO End Date: Oct/UNK/2019
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Congesutive Heart Failure]
	Start Date:	Jul/UNK/2019
	Ongoing:	YES

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**Header Text:** C4591001

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

**Form Version:** 10-Oct-2020 16:04

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Oct/13/2020
2.	Weight:	[307.4]
3.	Unit:	LB
4.	Height:	[73.0]
5.	Unit:	in
6.	Body Mass Index:	[40.6]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[98.7]
	Unit:	F
	Temperature Location:	FOREHEAD

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**Header Text:** C4591001

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

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** RANDOMIZATION

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Oct/13/2020
2.	Randomization Number:	[107094]
3.	Randomization Group:	[ ]

**Header Text:** C4591001

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

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/13/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR8BP0]
5.b	Sample ID	[BS71YG]
5.c	Sample ID	[BS71YH]

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**Header Text:** C4591001

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

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

**Site No:** 1221

**Subject No:** 12211002

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

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

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/13/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR8BNZ]
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**Header Text:** C4591001

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

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** VACCINATION

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[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:	Oct/13/2020 11:44
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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**Header Text:** C4591001

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

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[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:** 1221

**Subject No:** 12211002

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

**Form:** DATE OF VISIT

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Nov/2/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[96.4]
	Unit:	F
	Temperature Location:	FOREHEAD



**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1221

**Subject No:** 12211002

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

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

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**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:	Not Applicable _____ [ ]	<a href="#">Comments</a>

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[ ]
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**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** VACCINATION

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[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:	Nov/2/2020 09:52
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

**Header Text:** C4591001

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

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** DATE OF VISIT

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Dec/4/2020
2.	Erroneous Visit	

**Header Text:** C4591001

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

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/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	[BR8BX9]
5.b	Sample ID	[BS723Y]
5.c	Sample ID	[BS723Z]

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET  
on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Date of Visit**

1.	Date of Visit	Nov/3/2020
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 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Signs and Symptoms**

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

**Symptoms**

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

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

4.i	Symptoms:	VOMITING
	Was symptom present?	YES

**Symptoms - Other**

5.	Symptoms - Other Text:	[ ]
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**Header Text:** C4591001

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

**Form:** MICROBIOLOGY SPECIMEN

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Nov/3/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN  
on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Microbiology Specimen**

1.	Actual Date of Collection:	Nov/3/2020
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:	ABBOTT MOLECULAR REALTIME SARS-COV-2 ASSAY
7.	Test Result:	POSITIVE
8.	Comments/Findings/Details:	[ ]
9.	Trade Name Other, Specify:	[ ]

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Patient in hospital on 3 Nov. and was unable to do self swab.]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Nov/2/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Collected at V2, Nov.2 because patient admitted to hospital on Nov.3 with COVID-19 pneumonia. No self or site nasal swab collected on Nov. 3 illness visit, which was a televisit.]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR8BR7]
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090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION  
on Nov/03/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

[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?	YES Has the subject been in intensive care due to potential COVID-19 illness? NO
----	--	--

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

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

**Form:** HOSPITALIZATION DETAILS

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1.	HOSPITALIZATION STATUS	HOSPITAL	Nov/3/2020	NO Discharge Date:  Nov/6/2020	<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS  
on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Hospitalization Details**

1.	Hospitalization Category:	HOSPITALIZATION STATUS
2.	Hospitalization Term:	HOSPITAL
3.	Admission Date:	Nov/3/2020
4.	Ongoing?	NO Discharge Date: Nov/6/2020

**Header Text:** C4591001

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

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT  
on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Respiratory Treatment**

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

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS  
on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Illness Details**

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [Viral Pneumonia secondary to COVID-19]  Date of Diagnosis: Nov/3/2020
3.	Toxicity Grade:	3

**Header Text:** C4591001

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

**Form:** ILLNESS DETAILS - SEVERE

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE  
on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Illness Details**

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

Header Text: C4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 10-Oct-2020 15:58

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

#	Category for Lab Test	Vendor Name	Collect ion Date:	Specimen Type	Lab Result			Form Instance
1.	CLINICAL CHEMISTRY	Rehoboth McKinley Christian Hospital, 1901 Red Rock Dr, Gallup NM 87301	Nov/3/2020	BLOOD	<b>Sponsor-Defined Identifier</b>	<b>Test:</b>	<b>Result:</b>	<a href="#">Repeating Pages</a>
					329	C Reactive Protein_PX329	<0.5	
					30	Alanine Aminotransferase_PX30	50	
					28	Aspartate Aminotransferase_PX28	54	
					35	Alkaline Phosphatase_PX35	140	
					21	Bilirubin_PX21	0.5	
					47	Blood Urea Nitrogen_PX47	11	
					48	Creatinine_PX48	0.6	

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Nov/03/2020

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Lab Chemistry Details**

1.	Lab Panel:	CLINICAL CHEMISTRY
2.	Laboratory Name and Address	[Rehoboth McKinley Christian Hospital, 1901 Red Rock Dr, Gallup NM 87301]
3.	Collection Date:	Nov/3/2020
4.	Specimen Type:	BLOOD

**Lab Result**

5.a	Sponsor ID:	[329]
	Test:	C Reactive Protein_PX329
	Result:	[<0.5]
	Not Done:	
	LNMT	Low [0.0] High [0.5] Unit mg/dL
5.b	Sponsor ID:	[30]
	Test:	Alanine Aminotransferase_PX30
	Result:	[50]
	Not Done:	
	LNMT	Low [0] High [50] Unit U/L

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Nov/03/2020

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

5.c	Sponsor ID:	[28]
	Test:	Aspartate Aminotransferase_PX28
	Result:	[54]
	Not Done:	
	LNMT	Low [17] High [59] Unit U/L
5.d	Sponsor ID:	[35]
	Test:	Alkaline Phosphatase_PX35
	Result:	[140]
	Not Done:	
	LNMT	Low [38] High [126] Unit U/L
5.e	Sponsor ID:	[21]
	Test:	Bilirubin_PX21
	Result:	[0.5]
	Not Done:	
	LNMT	Low [0.2] High [1.3] Unit mg/dL

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Nov/03/2020

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

5.f	Sponsor ID:	[47]
	Test:	Blood Urea Nitrogen_PX47
	Result:	[11]
	Not Done:	
	LNMT	Low [9] High [20] Unit mg/dL

5.g	Sponsor ID:	[48]
	Test:	Creatinine_PX48
	Result:	[0.6]
	Not Done:	
	LNMT	Low [0.7] High [1.3] Unit mg/dL

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 10-Oct-2020 16:02

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date	Specimen Type	Lab Result	Form Instance																																	
1.	HEMATOLOGY	Rehoboth McKinley Christian Hospital, 1901 Red Rock Dr, Gallup NM 87301	Nov/3/2020	BLOOD	<table border="1"> <thead> <tr> <th>Sponsor-Defined Identifier</th> <th>Test:</th> <th>Result:</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Hemoglobin_PX1</td> <td>16.1</td> </tr> <tr> <td>2</td> <td>Hematocrit_PX2</td> <td>48.4</td> </tr> <tr> <td>3</td> <td>Erythrocytes_PX3</td> <td>5.41</td> </tr> <tr> <td>5</td> <td>Platelets_PX5</td> <td>198</td> </tr> <tr> <td>7</td> <td>Leukocytes_PX7</td> <td>5.70</td> </tr> <tr> <td>608</td> <td>Neutrophils_PX608</td> <td>3.8</td> </tr> <tr> <td>609</td> <td>Eosinophils_PX609</td> <td>0.0</td> </tr> <tr> <td>612</td> <td>Monocytes_PX612</td> <td>1.0</td> </tr> <tr> <td>610</td> <td>Basophils_PX610</td> <td>0.0</td> </tr> <tr> <td>611</td> <td>Lymphocytes_PX611</td> <td>0.8</td> </tr> </tbody> </table>	Sponsor-Defined Identifier	Test:	Result:	1	Hemoglobin_PX1	16.1	2	Hematocrit_PX2	48.4	3	Erythrocytes_PX3	5.41	5	Platelets_PX5	198	7	Leukocytes_PX7	5.70	608	Neutrophils_PX608	3.8	609	Eosinophils_PX609	0.0	612	Monocytes_PX612	1.0	610	Basophils_PX610	0.0	611	Lymphocytes_PX611	0.8	<a href="#">Repeating Pages</a>
Sponsor-Defined Identifier	Test:	Result:																																					
1	Hemoglobin_PX1	16.1																																					
2	Hematocrit_PX2	48.4																																					
3	Erythrocytes_PX3	5.41																																					
5	Platelets_PX5	198																																					
7	Leukocytes_PX7	5.70																																					
608	Neutrophils_PX608	3.8																																					
609	Eosinophils_PX609	0.0																																					
612	Monocytes_PX612	1.0																																					
610	Basophils_PX610	0.0																																					
611	Lymphocytes_PX611	0.8																																					

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Laboratory Data Hematology**

1.	Lab Panel:	HEMATOLOGY
2.	Laboratory Name and Address	[Rehoboth McKinley Christian Hospital, 1901 Red Rock Dr, Gallup NM 87301]
3.	Collection Date:	Nov/3/2020
4.	Specimen Type:	BLOOD

**Lab Result**

5.a	Sponsor ID:	[1]
	Test:	Hemoglobin_PX1
	Result:	[16.1]
	Not Done:	
	LNMT	Low [14.0] High [18.0] Unit g/dL
5.b	Sponsor ID:	[2]
	Test:	Hematocrit_PX2
	Result:	[48.4]
	Not Done:	
	LNMT	Low [41.0] High [49.0] Unit %

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

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5.c	Sponsor ID:	[3]
	Test:	Erythrocytes_PX3
	Result:	[5.41]
	Not Done:	
	LNMT	Low [4.00] High [5.60] Unit 10^6/cu mm
5.d	Sponsor ID:	[5]
	Test:	Platelets_PX5
	Result:	[198]
	Not Done:	
	LNMT	Low [180] High [430] Unit 10^6/cu mm
5.e	Sponsor ID:	[7]
	Test:	Leukocytes_PX7
	Result:	[5.70]
	Not Done:	
	LNMT	Low [4.5] High [11.0] Unit 10^6/cu mm

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

5.f	Sponsor ID:	[608]
	Test:	Neutrophils_PX608
	Result:	[3.8]
	Not Done:	
	LNMT	Low [1.5] High [8.0] Unit 10^6/cu mm
5.g	Sponsor ID:	[609]
	Test:	Eosinophils_PX609
	Result:	[0.0]
	Not Done:	
	LNMT	Low [0.0] High [1.0] Unit 10^6/cu mm
5.h	Sponsor ID:	[612]
	Test:	Monocytes_PX612
	Result:	[1.0]
	Not Done:	
	LNMT	Low [0.0] High [1.0] Unit 10^6/cu mm

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

5.i	Sponsor ID:	[610]
	Test:	Basophils_PX610
	Result:	[0.0]
	Not Done:	
	LNMT	Low [0.0] High [0.5] Unit 10^6/cu mm
5.j	Sponsor ID:	[611]
	Test:	Lymphocytes_PX611
	Result:	[0.8]
	Not Done:	
	LNMT	Low [0.9] High [4.4] Unit 10^6/cu mm

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**Header Text:** C4591001

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

**Form:** VITAL SIGNS - COVID

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

#	Date:	Vital Signs Details			Form Instance
1.	Nov/3/2020	<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>
		1	153	97	

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID  
on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Vital Signs**

1.	Date:	Nov/3/2020
----	-------	------------

**Vital Signs Details**

2.a	Record Identifier:	1
	Systolic:	[153]
	Diastolic:	[97]
	Respiratory Rate in respirations/minute:	[32]
	Heart Rate in beats/minute:	[72]

**Header Text:** C4591001

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

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

**Form Version:** 10-Oct-2020 16:04

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

#	Date:	Vital Signs Details		Form Instance
1.	Nov/3/2020	<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>
		1	95.0	

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
on Nov/03/2020

**Form Version:** 10-Oct-2020 16:04

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Vital Signs**

1.	Date:	Nov/3/2020
----	-------	------------

**Vital Signs Details**

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[95.0]



**Header Text:** C4591001

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

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS  
on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Oxygenation Parameters**

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

**Header Text:** C4591001

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

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS  
on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Concomitant Medications**

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

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

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

**Form:** IMAGING

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Nov/3/2020	CHEST	X-RAY	NORMAL	<a href="#">Repeating Pages</a>
2.	Nov/3/2020	CHEST	CT SCAN	ABNORMAL <i>If abnormal, specify findings:</i>  Small patchy density in R Upper lobe, likely inflammatory/infectious with minor bibasilar subsegmental atelectasis; R coronary atherosclerosis vs. stent	<a href="#">Repeating Pages</a>

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** IMAGING  
on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Imaging**

1.	Date of Assessment:	Nov/3/2020
2.	Location of Assessment:	CHEST
3.	Type of Imaging Exam:	X-RAY
4.	Assessment:	NORMAL

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** IMAGING  
on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

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**Imaging**

1.	Date of Assessment:	Nov/3/2020
2.	Location of Assessment:	CHEST
3.	Type of Imaging Exam:	CT SCAN
4.	Assessment:	ABNORMAL If abnormal, specify findings: [Small patchy density in R Upper lobe, likely inflammatory/infectious with minor bibasilar subsegmental atelectasis; R coronary atherosclerosis vs. stent]

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET  
on Feb/28/2021

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Date of Visit**

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

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_B
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Feb/28/2021

**Form Version:** 20-Feb-2021 02:17

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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**Generated Time (GMT):** 29-Mar-2021 13:11

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**Signs and Symptoms**

1.	Date of Assessment:	Feb/28/2021
2.	Date of First Symptom Started:	Feb/26/2021
3.	Symptoms Ongoing?	NO
	Date of Last Symptom Resolved:	Mar/2/2021

**Symptoms**

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

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Feb/28/2021

**Form Version:** 20-Feb-2021 02:17

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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**Generated Time (GMT):** 29-Mar-2021 13:11

4.i	Symptoms:	VOMITING
	Was symptom present?	NO

**Symptoms - Other**

5.a	Symptoms - Other Text:	[nasal congestion]
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** MICROBIOLOGY SPECIMEN

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Mar/4/2021	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN  
on Feb/28/2021

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Microbiology Specimen**

1.	Actual Date of Collection:	Mar/4/2021	<a href="#">Comments</a>
2.	Specimen Type:	SWABBED MATERIAL	<a href="#">Comments</a>
3.	Specimen Collection Location:	NASOPHARYNX	<a href="#">Comments</a>
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	<a href="#">Comments</a>
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Comments</a>
6.	Trade Name:	CEPHEID XPERT XPRESS SARS-COV-2 TEST	<a href="#">Comments</a>
7.	Test Result:	POSITIVE	<a href="#">Comments</a>
8.	Comments/Findings/Details:	[Cepheid IQC4PLEX]	<a href="#">Comments</a>
9.	Trade Name Other, Specify:	[ ]	<a href="#">Comments</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Feb/28/2021

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Feb/27/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[CV55142]
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
on Feb/28/2021

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION  
on Feb/28/2021

**Form Version:** 20-Feb-2021 02:19

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Health Care Utilization**

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

**Health Care Utilization Other**

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

**Health Care Utilization**

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

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** HOSPITALIZATION DETAILS

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS  
on Feb/28/2021

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Hospitalization Details**

1.	Hospitalization Category:	Not Applicable _____	<a href="#">Comments</a>
2.	Hospitalization Term:	Not Applicable _____	<a href="#">Comments</a>
3.	Admission Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Ongoing?	Not Applicable _____	<a href="#">Comments</a>

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT  
on Feb/28/2021

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Respiratory Treatment**

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

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** ILLNESS DETAILS  
on Feb/28/2021

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

**Form Status:** Data Complete, Verified

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Illness Details**

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [COVID-19]  Date of Diagnosis: Mar/4/2021
3.	Toxicity Grade:	1

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**Visit:** POT\_COVID\_ILL 2

**Form:** ILLNESS DETAILS - SEVERE

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE  
on Feb/28/2021

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Illness Details**

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

Header Text: C4591001

Visit: POT\_COVID\_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 10-Oct-2020 15:58

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Feb/28/2021

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Lab Chemistry Details**

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

**Lab Result**

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

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Feb/28/2021

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Feb/28/2021

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Feb/28/2021

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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

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Header Text: C4591001

Visit: POT\_COVID\_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 10-Oct-2020 16:02

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Feb/28/2021

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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**Generated Time (GMT):** 29-Mar-2021 13:11

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**Laboratory Data Hematology**

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

**Lab Result**

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

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Feb/28/2021

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Feb/28/2021

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Feb/28/2021

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Feb/28/2021

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Feb/28/2021

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** VITAL SIGNS - COVID

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

#	Date:	Vital Signs Details			Form Instance
1.	Not Applicable	<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>
		Not Applicable	Not Applicable	Not Applicable	

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** VITAL SIGNS - COVID  
on Feb/28/2021

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Vital Signs**

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

**Vital Signs Details**

2.a	Record Identifier:	Not Applicable _____ 1	
	Systolic:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Diastolic:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Respiratory Rate in respirations/minute:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Heart Rate in beats/minute:	Not Applicable _____ [ ]	<a href="#">Comments</a>

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

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

**Form Version:** 10-Oct-2020 16:04

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

#	Date:	Vital Signs Details		Form Instance
1.	Not Applicable	<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>
		Not Applicable	Not Applicable	

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
on Feb/28/2021

**Form Version:** 10-Oct-2020 16:04

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Vital Signs**

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

**Vital Signs Details**

2.a	Record Identifier:	Not Applicable _____ 1	
	SPO2 Pulse Oximetry %	Not Applicable _____ [ ]	<a href="#">Comments</a>

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS  
on Feb/28/2021

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Oxygenation Parameters**

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



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS  
on Feb/28/2021

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Concomitant Medications**

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

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** IMAGING

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** IMAGING  
on Feb/28/2021

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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

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**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled **Form:** DATE OF VISIT - ILLNESS CONVALESCENT  
Visit on Dec/04/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Date of Visit**

1.	Date of Visit	Dec/4/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
Visit on Dec/04/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/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	[BR8BX8]
5.b	Sample ID	[BS723W]
5.c	Sample ID	[BS723X]

**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:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

**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:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** C4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1. DELETED	ADVERSE EVENT	1	COVID-19	Nov/1/2020 UNK:UNK	YES	<a href="#">Repeating Pages</a>

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1221

Subject No: 12211002

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[+]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[COVID-19]
4.	Start Date Time:	Nov/1/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
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).	<p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect? NO</p> <p>Did this serious event result in death? NO</p> <p>Did this serious event require or prolong hospitalization? YES</p> <p>Did this serious event result in persistent or significant disability/incapacity? NO</p> <p>Is this serious event life threatening? NO</p> <p>Other medically important serious event NO</p>
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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9.	Is this event related to study treatment:	<del>NOT RELATED</del> If Not Related to study treatment(s), this event is due to: <del>OTHER</del> If Other, specify: [Viral infection]
10.	Latest Action Taken with Study Treatment:	<del>NOT APPLICABLE</del>
11.	Was a Concomitant Medication given?	<del>YES</del>
12.	Was a Non-Drug Treatment given?	<del>YES</del>
13.	What was the outcome of this adverse event?:	<del>NOT RECOVERED/NOT RESOLVED</del>
14.	Did the adverse event cause the subject to be discontinued from the study?	<del>NO</del>
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020427759]

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**Header Text:** C4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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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: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1. DELETED						<a href="#">Repeating Pages</a>
2. DELETED						<a href="#">Repeating Pages</a>
3. DELETED						<a href="#">Repeating Pages</a>
4. DELETED						<a href="#">Repeating Pages</a>
5. DELETED						<a href="#">Repeating Pages</a>
6. DELETED						<a href="#">Repeating Pages</a>
7. DELETED						<a href="#">Repeating Pages</a>
8. DELETED						<a href="#">Repeating Pages</a>
9. DELETED						<a href="#">Repeating Pages</a>
10. DELETED						<a href="#">Repeating Pages</a>
11. DELETED						<a href="#">Repeating Pages</a>
12. DELETED						<a href="#">Repeating Pages</a>

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Incomplete, Data Complete, Deleted, Verified

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

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**Concomitant Medications**

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

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**Header Text:** C4591001**Visit:** Logs - Unscheduled**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS**Form Version:** 22-Apr-2020 21:03**Form Status:** Incomplete, Data Complete, Deleted, Verified**Site No:** 1221**Site Name:** (1221) Center for American Indian Health - Gallup**Subject No:** 12211002**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11

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**Concomitant Medications**

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



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Incomplete, Data Complete, Deleted, Verified

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Concomitant Medications**

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

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Incomplete, Data Complete, Deleted, Verified

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Concomitant Medications**

1.	What is the medication identifier?	[ ]
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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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**Site No:** 1221

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**Concomitant Medications**

1.	What is the medication identifier?	[ ]
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5.	Date:	//

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**Concomitant Medications**

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

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**Concomitant Medications**

1.	What is the medication identifier?	[ ]
2.	Category:	
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**Concomitant Medications**

1.	What is the medication identifier?	[ ]
2.	Category:	
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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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**Form Status:** Incomplete, Data Complete, Deleted, Verified

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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**Concomitant Medications**

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2.	Category:	
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**Concomitant Medications**

1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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**Form Status:** Incomplete, Data Complete, Deleted, Verified

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

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**Concomitant Medications**

1.	What is the medication identifier?	[ ]
2.	Category:	
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**Concomitant Medications**

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

**Header Text:** C4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

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

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#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1. DELETED	1	CORTICOSTEROIDS	NO	Dexamethasone (Decadron)	6	<a href="#">Repeating Pages</a>
2. DELETED	2	CORTICOSTEROIDS	NO	Dexamethasone	6	<a href="#">Repeating Pages</a>
3. DELETED	3	CONCOMITANT IMMUNOSUPPRESSIVE THERAPY	NO	Remdesivir	200	<a href="#">Repeating Pages</a>
4. DELETED	4	CONCOMITANT IMMUNOSUPPRESSIVE THERAPY	NO	Remdesivir	100	<a href="#">Repeating Pages</a>

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Subject No: 12211002

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Data Complete, Deleted, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

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**Concomitant Medications**

1.	What is the medication identifier?	[4]
2.	Category:	CORTICOSTEROIDS
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).	[Dexamethasone (Decadron)]
5.	Dose:	[6]
6.	Dose Unit:	mg
7.	Dose Frequency:	QD
8.	Route:	INTRAVENOUS
9.	Start Date:	Nov/3/2020
10.	Ongoing?	NO  End Date: Nov/6/2020

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**Header Text:** C4591001

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**Site No:** 1221

**Subject No:** 12211002

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**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site Name:** (1221) Center for American Indian Health - Gallup

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**Concomitant Medications**

1.	What is the medication identifier?	[2]
2.	Category:	CORTICOSTEROIDS
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).	[Dexamethasone]
5.	Dose:	[6]
6.	Dose Unit:	mg
7.	Dose Frequency:	QD
8.	Route:	ORAL
9.	Start Date:	Nov/7/2020
10.	Ongoing?	NO End Date: Nov/10/2020

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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**Site No:** 1221

**Subject No:** 12211002

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site Name:** (1221) Center for American Indian Health - Gallup

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**Concomitant Medications**

1.	What is the medication identifier?	[3]
2.	Category:	CONCOMITANT IMMUNOSUPPRESSIVE THERAPY
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).	[Remdesivir]
5.	Dose:	[200]
6.	Dose Unit:	mg
7.	Dose Frequency:	ONCE
8.	Route:	INTRAVENOUS
9.	Start Date:	Nov/3/2020
10.	Ongoing?	NO End Date: Nov/3/2020

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

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**Concomitant Medications**

1.	What is the medication identifier?	[4]
2.	Category:	CONCOMITANT IMMUNOSUPPRESSIVE THERAPY
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).	[Remdesivir]
5.	Dose:	[100]
6.	Dose Unit:	mg
7.	Dose Frequency:	QD
8.	Route:	INTRAVENOUS
9.	Start Date:	Nov/4/2020
10.	Ongoing?	NO End Date: Nov/6/2020

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**Header Text:** C4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** RADIATION TREATMENT

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Radiation Treatment**

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

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**Header Text:** C4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

#	Transfusion Type	Date of Transfusion	Form Instance
1.	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** TRANSFUSIONS

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

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1.	Transfusion Type:	Not Applicable _____	<a href="#">Comments</a>
2.	Date of Transfusion:	Not Applicable _____ //	<a href="#">Comments</a>

**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:** 1221

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**Subject No:** 12211002

**Subject Initials:** ---

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

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**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:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

**Unplanned Assessments**

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

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

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**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:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

**Vital Signs**

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

**Vital Signs Details**

2.	Record Identifier:	
	Temperature:	[ ]
	Unit:	
	Temperature Location:	

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

**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?	

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**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:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

**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:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

**Contact Outcome**

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

**Header Text:** C4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** DISPOSITION - TREATMENT

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Disposition - Treatment**

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

**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:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**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, Verified

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Further Vaccination Confirmation**

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

**Header Text:** C4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**Disposition - Follow-Up**

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

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** TREATMENT UNBLINDED

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**Withdrawal Of Consent**

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



**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**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:** 1221

**Subject No:** 12211002

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

**Form:** DATE OF VISIT

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** INFORMED CONSENT - FURTHER VACCINATION

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Informed Consent - Further Vaccination**

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

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

**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:** 1221

**Subject No:** 12211002

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

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

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

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

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/1/2021
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	[BRJ42L]
5.b	Sample ID	[BS6ZGG]
5.c	Sample ID	[BS6ZGH]

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1221

**Subject No:** 12211002

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

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

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/1/2021
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	[BRJ42H]
-----	-----------	----------

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** VACCINATION

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[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/1/2021 12:43
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)



**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** DATE OF VISIT

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**eCRF Audit Trail History**

**Date of Visit**

1.	Date of Visit	Feb/22/2021
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1221

**Subject No:** 12211002

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

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

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**eCRF Audit Trail History**

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/22/2021
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	[BRJ43Y]
-----	-----------	----------

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** V102\_VAX4

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** VACCINATION

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[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/22/2021 16:44
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
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

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**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:** 1221

**Subject No:** 12211002

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

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**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:** 1221

**Subject No:** 12211002

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**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:** 1221

**Subject No:** 12211002

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

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**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:** 1221

**Subject No:** 12211002

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**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:** 1221

**Subject No:** 12211002

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

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**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:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

**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:** 1221

**Subject No:** 12211002

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

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Dec/4/2020

**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:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

[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:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Jane Halpern	Approved	Mar-09-2021 10:12:16 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, JaneHalpern, 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.

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** MAIN INFORMED CONSENT - Comments

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
Form	Oct-15-2020 09:07:01 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Per protocol, visit 1 can be split over two days

**Header Text:** C4591001

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

**Form Version:** 10-Oct-2020 16:00

**Site No:** 1221

**Subject No:** 12211002

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

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

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
Form	Oct-14-2020 12:23:54 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
4	Nov-17-2020 11:27:57 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Not Applicable



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-11-2020 08:25:44 (UTC-07:00) Mountain Time (US & Canada)	Jane Halpern (b) (4)	Received only 2L O2 by nasal canula Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
1	Nov-11-2020 08:25:44 (UTC-07:00) Mountain Time (US & Canada)	Jane Halpern (b) (4)	Received only 2L O2 by nasal canula Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

[Back to Form](#)

Item	Date	User	Comment
2	Nov-11-2020 08:25:44 (UTC-07:00) Mountain Time (US & Canada)	Jane Halpern (b) (4)	Received only 2L O2 by nasal canula Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
3	Nov-11-2020 08:25:44 (UTC-07:00) Mountain Time (US & Canada)	Jane Halpern (b) (4)	Received only 2L O2 by nasal canula Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

[Back to Form](#)

Item	Date	User	Comment
4	Nov-11-2020 08:25:44 (UTC-07:00) Mountain Time (US & Canada)	Jane Halpern (b) (4)	Received only 2L O2 by nasal canula Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
5	Nov-11-2020 08:25:44 (UTC-07:00) Mountain Time (US & Canada)	Jane Halpern (b) (4)	Received only 2L O2 by nasal canula Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
6	Nov-11-2020 08:25:44 (UTC-07:00) Mountain Time (US & Canada)	Jane Halpern (b) (4)	Received only 2L O2 by nasal canula Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments  
on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
Form	Nov-11-2020 09:37:35 (UTC-07:00) Mountain Time (US & Canada)	Jane Halpern (b) (4)	Not Applicable



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments  
on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
1	Nov-11-2020 09:37:35 (UTC-07:00) Mountain Time (US & Canada)	Jane Halpern (b) (4)	Not Applicable
1	Nov-11-2020 09:32:45 (UTC-07:00) Mountain Time (US & Canada)	Jane Halpern (b) (4)	No severe illness parameters present
1	Nov-11-2020 09:32:07 (UTC-07:00) Mountain Time (US & Canada)	Jane Halpern (b) (4)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments  
on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
2	Nov-11-2020 09:37:35 (UTC-07:00) Mountain Time (US & Canada)	Jane Halpern (b) (4)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments  
on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
3	Nov-11-2020 09:37:35 (UTC-07:00) Mountain Time (US & Canada)	Jane Halpern (b) (4)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments  
on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
4	Nov-11-2020 09:37:35 (UTC-07:00) Mountain Time (US & Canada)	Jane Halpern (b) (4)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments  
on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
Form	Nov-11-2020 09:31:25 (UTC-07:00) Mountain Time (US & Canada)	Jane Halpern (b) (4)	No ABG's done. _____ Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments  
on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
1	Nov-11-2020 09:31:25 (UTC-07:00) Mountain Time (US & Canada)	Jane Halpern (b) (4)	No ABG's done. Not Applicable
1	Nov-11-2020 09:27:22 (UTC-07:00) Mountain Time (US & Canada)	Jane Halpern (b) (4)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments  
on Nov/03/2020

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

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**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
2	Nov-11-2020 09:31:25 (UTC-07:00) Mountain Time (US & Canada)	Jane Halpern (b) (4)	No ABG's done. Not Applicable

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Item	Date	User	Comment
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**Header Text:** C4591001

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**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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**Site No:** 1221

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
Form	Nov-11-2020 09:18:11 (UTC-07:00) Mountain Time (US & Canada)	Jane Halpern (b) (4)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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

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

**Site No:** 1221

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
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**Header Text:** C4591001

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Item	Date	User	Comment
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
6	Nov-11-2020 09:18:11 (UTC-07:00) Mountain Time (US & Canada)	Jane Halpern (b) (4)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Feb/28/2021

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
Form	Mar-05-2021 15:42:03 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	
Form	Mar-01-2021 16:24:22 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Not medically attended Not Applicable



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Feb/28/2021

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
1	Mar-05-2021 15:42:03 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	
1	Mar-01-2021 16:24:22 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Not medically attended Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
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**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
2	Mar-05-2021 15:42:03 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	
2	Mar-01-2021 16:24:22 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Not medically attended Not Applicable

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Item	Date	User	Comment
3	Mar-05-2021 15:42:03 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	
3	Mar-01-2021 16:24:22 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Not medically attended Not Applicable

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Item	Date	User	Comment
4	Mar-05-2021 15:42:03 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	
4	Mar-01-2021 16:24:22 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Not medically attended Not Applicable

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

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Item	Date	User	Comment
5	Mar-05-2021 15:42:03 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	
5	Mar-01-2021 16:24:22 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Not medically attended Not Applicable

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**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
6	Mar-05-2021 15:42:03 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	
6	Mar-01-2021 16:24:22 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Not medically attended Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
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**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
7	Mar-05-2021 15:42:03 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	
7	Mar-01-2021 16:24:22 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Not medically attended Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Feb/28/2021

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

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**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
8	Mar-05-2021 15:42:03 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	
8	Mar-01-2021 16:24:22 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Not medically attended Not Applicable



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Feb/28/2021

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
9	Mar-05-2021 15:42:03 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	
9	Mar-01-2021 16:24:22 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Not medically attended Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - Comments  
on Feb/28/2021

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
Form	Mar-01-2021 16:28:29 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	not medically attended
			Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - Comments  
on Feb/28/2021

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
1	Mar-01-2021 16:28:29 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	not medically attended
			Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - Comments  
on Feb/28/2021

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
2	Mar-01-2021 16:28:29 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	not medically attended
			Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - Comments  
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Item	Date	User	Comment
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Item	Date	User	Comment
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Feb/28/2021

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

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

**Site No:** 1221

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**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
Form	Mar-01-2021 16:29:41 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Not medically attended
			Not Applicable

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Feb/28/2021

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Item	Date	User	Comment
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Item	Date	User	Comment
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments  
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**Form Version:** 17-Jul-2020 21:55

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

**Site No:** 1221

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
Form	Mar-01-2021 16:30:26 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments  
on Feb/28/2021

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
1	Mar-01-2021 16:30:26 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments  
on Feb/28/2021

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

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

**Form Version:** 10-Oct-2020 15:58

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5 h	Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	not medically attended
			Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021

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

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
5 h	Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	not medically attended
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**Header Text:** C4591001

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Item	Date	User	Comment
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Item	Date	User	Comment
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Comments  
on Feb/28/2021

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
Form	Mar-01-2021 16:32:39 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	No vitals taken
			Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Comments  
on Feb/28/2021

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
1	Mar-01-2021 16:32:39 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	No vitals taken
			Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Comments  
on Feb/28/2021

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
2.a	Mar-01-2021 16:32:39 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	No vitals taken
			Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Comments  
on Feb/28/2021

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

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Item	Date	User	Comment
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**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
2.a	Mar-01-2021 16:32:39 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	No vitals taken
			Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments on Feb/28/2021

**Form Version:** 10-Oct-2020 16:04

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
Form	Mar-01-2021 16:33:03 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments on Feb/28/2021

**Form Version:** 10-Oct-2020 16:04

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
1	Mar-01-2021 16:33:03 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Not Applicable



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments on Feb/28/2021

**Form Version:** 10-Oct-2020 16:04

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
2.a	Mar-01-2021 16:33:03 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments  
on Feb/28/2021

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
Form	Mar-01-2021 16:33:22 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments  
on Feb/28/2021

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
1	Mar-01-2021 16:33:22 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments  
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Item	Date	User	Comment
2	Mar-01-2021 16:33:22 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

**Header Text:** C4591001

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Item	Date	User	Comment
3	Mar-01-2021 16:33:22 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
Form	Mar-01-2021 16:33:56 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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

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

**Site No:** 1221

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**Subject No:** 12211002

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**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
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**Header Text:** C4591001

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Item	Date	User	Comment
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Item	Date	User	Comment
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**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
Form	Mar-01-2021 16:34:47 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** IMAGING - Comments  
on Feb/28/2021

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

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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
4	Mar-01-2021 16:34:47 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** RADIATION TREATMENT - Comments

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
Form	Nov-11-2020 10:43:11 (UTC-07:00) Mountain Time (US & Canada)	Jane Halpern (b) (4)	Not Applicable

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** RADIATION TREATMENT - Comments

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
1	Nov-11-2020 10:43:11 (UTC-07:00) Mountain Time (US & Canada)	Jane Halpern (b) (4)	Not Applicable

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1221

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**Form:** RADIATION TREATMENT - Comments

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
2	Nov-11-2020 10:43:11 (UTC-07:00) Mountain Time (US & Canada)	Jane Halpern (b) (4)	Not Applicable

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** RADIATION TREATMENT - Comments

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
3	Nov-11-2020 10:43:11 (UTC-07:00) Mountain Time (US & Canada)	Jane Halpern (b) (4)	Not Applicable

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** RADIATION TREATMENT - Comments

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
4	Nov-11-2020 10:43:11 (UTC-07:00) Mountain Time (US & Canada)	Jane Halpern (b) (4)	Not Applicable

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** RADIATION TREATMENT - Comments

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
5	Nov-11-2020 10:43:11 (UTC-07:00) Mountain Time (US & Canada)	Jane Halpern (b) (4)	Not Applicable

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** RADIATION TREATMENT - Comments

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
6	Nov-11-2020 10:43:11 (UTC-07:00) Mountain Time (US & Canada)	Jane Halpern (b) (4)	Not Applicable



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** TRANSFUSIONS - Comments

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
Form	Nov-11-2020 10:43:31 (UTC-07:00) Mountain Time (US & Canada)	Jane Halpern (b) (4)	Not Applicable

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** TRANSFUSIONS - Comments

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
1	Nov-11-2020 10:43:31 (UTC-07:00) Mountain Time (US & Canada)	Jane Halpern (b) (4)	Not Applicable

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** TRANSFUSIONS - Comments

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
2	Nov-11-2020 10:43:31 (UTC-07:00) Mountain Time (US & Canada)	Jane Halpern (b) (4)	Not Applicable

**Header Text:** C4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Item	Date	User	Comment
Form	Feb-01-2021 15:18:59 (UTC-07:00) Mountain Time (US & Canada)	(b)(4),(b)(6)	Not Applicable

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Jane Halpern	Approved	Mar-09-2021 10:12:16 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed

**Affidavit:**

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

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

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

(b) (6)	N/A	Mar-05-2021 11:51:14 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Jane Halpern	Approved	Mar-04-2021 09:11:35 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, JaneHalpern, 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	Feb-01-2021 15:11:48 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (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:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

Laura Hammit	Approved	Jan-12-2021 21:34:11 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, LauraHammit, 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-07-2021 17:50:46 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Laura Hammit	Approved	Dec-04-2020 23:08:06 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Dec-04-2020 12:04:22 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Laura Hammit	Approved	Nov-17-2020 18:14:43 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (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:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

**Affidavit:**

By my dated signature below, I, LauraHammit, 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.

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** COHORT\_SELECTION - eCRF Audit Trail History

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Oct-14-2020 12:18:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-14-2020 12:18:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry



Header Text: C4591001

Visit: COHORT\_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1221

Subject No: 12211002

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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**I. Consent Was:**

Date	Location	User	Value	Reason
Oct-19-2020 00:07:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Response satisfies query.
Oct-15-2020 12:47:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Query 1: Answered	Consent/screening visit was 12 Oct.2020. Vax1 Visit, per protocol, was the following day (13 Oct. 2020)
Oct-14-2020 23:48:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Query 1: Reissued:Opened	DM1: Thanks for the response. Kindly confirm the reason why the Date Informed Consent Obtained is different from the Date of Visit.
Oct-14-2020 12:29:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Answered	Original value is correct
Oct-14-2020 12:18:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date Informed Consent Obtained is not the same as the Date of Visit. Please correct as necessary.
Oct-14-2020 12:11:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtain ed  Oct/12/2020	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: COHORT\_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1221

Subject No: 12211002

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Subject ID**

Date	Location	User	Value	Reason
Oct-14-2020 09:16:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12211002	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Oct-14-2020 09:16:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) 1977	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Oct-14-2020 12:12:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Oct-14-2020 12:12:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-14-2020 12:12:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> AMERICAN INDIAN OR ALAS KA NATIVE	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-14-2020 12:18:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> Oct/13/2020	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:52

Site No: 1221

Subject No: 12211002

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Oct-14-2020 12:25:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> Oct/13/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-14-2020 12:25:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-14-2020 12:25:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1221

Subject No: 12211002

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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*1.a*

Date	Location	User	Value	Reason
Oct-15-2020 12:54:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Num</b> 1 <b>ber:</b> <b>Medical Histor</b> Coronary Stent pl <b>y Term:</b> acement <b>Start Date:</b> Jul/UNK/2019 <b>Ongoing:</b> NO End Date: Jul/UNK/2019	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Oct-15-2020 12:54:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

*1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:*

Date	Location	User	Value	Reason
Oct-15-2020 12:54:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Coronary Stent placement	Initial Entry

*1.a Start Date:*

Date	Location	User	Value	Reason
Oct-15-2020 12:54:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Jul/UNK/2019	Initial Entry

*1.a Ongoing:*

Date	Location	User	Value	Reason
Oct-15-2020 12:54:33 (UTC-07:00) Mountain	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

Time (US & Canada)			End Date:	
			Jul/UNK/2019	

**I.b**

Date	Location	User	Value	Reason
Oct-15-2020 13:36:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> <b>Line/MH Numbr:</b> 2 <b>Medical History Term:</b> Circumcision <b>Start Date:</b> Oct/UNK/2019 <b>Ongoing:</b> NO End Date: Oct/UNK/2020	Transcription Error
Oct-15-2020 12:55:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Numbr:</b> 2 <b>Medical History Term:</b> Circumcision <b>Start Date:</b> Oct/UNK/2020 <b>Ongoing:</b> NO End Date: Oct/UNK/2020	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1221

Subject No: 12211002

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

***1.b Line/MH Number:***

Date	Location	User	Value	Reason
Oct-15-2020 12:55:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

***1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Oct-15-2020 12:55:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Circumcision	Initial Entry

***1.b Start Date:***

Date	Location	User	Value	Reason
Oct-15-2020 13:36:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-15-2020 13:36:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Oct/UNK/2019	Transcription Error
Oct-15-2020 13:32:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Start Date is after or equal to the first vaccination date 13/Oct/2020. Please review and update as appropriate.
Oct-15-2020 12:55:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Oct/UNK/2020	Initial Entry

***1.b Ongoing:***

Date	Location	User	Value	Reason
Oct-15-2020 12:55:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> NO End Date:  Oct/UNK/2020	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1221

Subject No: 12211002

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

I.c

Date	Location	User	Value	Reason
Oct-15-2020 12:57:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 3 <b>Medical History Term:</b> Hypertension <b>Start Date:</b> Jul/15/2020 <b>Ongoing:</b> YES	Initial Entry

I.c Line/MH Number:

Date	Location	User	Value	Reason
Oct-15-2020 12:57:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 12:57:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Hypertension	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Oct-15-2020 12:57:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Jul/15/2020	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Oct-15-2020 12:57:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> YES	Initial Entry

I.d

Date	Location	User	Value	Reason
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090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)



**Header Text:** C4591001

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

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

Oct-15-2020 13:13:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> <b>Line/MH Num 4</b> <b>ber:</b> <b>Medical Histo</b> Coronary Arter <b>ry Term:</b> y Disease <b>Start Date:</b> Jul/15/2020 <b>Ongoing:</b> YES	Changed Information
Oct-15-2020 12:57:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 4 <b>Medical History Te</b> ASCVD <b>rm:</b> <b>Start Date:</b> Jul/15/20 20 <b>Ongoing:</b> YES	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1221**Subject No:** 12211002**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1221) Center for American Indian Health - Gallup**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:11***I.d Line/MH Number:***

Date	Location	User	Value	Reason
Oct-15-2020 12:57:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 13:13:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Coronary Artery Disease	Changed Information
Oct-15-2020 12:57:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> ASCVD	Initial Entry

***I.d Start Date:***

Date	Location	User	Value	Reason
Oct-15-2020 12:57:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Jul/15/2020	Initial Entry

***I.d Ongoing:***

Date	Location	User	Value	Reason
Oct-15-2020 12:57:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> YES	Initial Entry

***I.e***

Date	Location	User	Value	Reason
Oct-15-2020 12:58:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 5 <b>Medical History Term:</b> Hypercholesterolemia <b>Start Date:</b> Jul/15/2020 <b>Ongoing:</b> YES	Initial Entry

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Subject No: 12211002

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

*I.e Line/MH Number:*

Date	Location	User	Value	Reason
Oct-15-2020 12:58:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 5	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 12:58:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<u>Data Entry:</u> Hypercholesterolemia	Initial Entry

*I.e Start Date:*

Date	Location	User	Value	Reason
Oct-15-2020 12:58:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<u>Data Entry:</u> Jul/15/2020	Initial Entry

*I.e Ongoing:*

Date	Location	User	Value	Reason
Oct-15-2020 12:58:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<u>Data Entry:</u> YES	Initial Entry

*I.f*

Date	Location	User	Value	Reason
Oct-15-2020 12:59:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> <b>Line/MH Number</b> 6 : <b>Medical History T</b> Diabetes Typ <b>erm:</b> e 2 <b>Start Date:</b> UNK/UNK/2 000 <b>Ongoing:</b> YES	Initial Entry

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Subject No: 12211002

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

*1.f Line/MH Number:*

Date	Location	User	Value	Reason
Oct-15-2020 12:59:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 6	Initial Entry

*1.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:*

Date	Location	User	Value	Reason
Oct-15-2020 12:59:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<u>Data Entry:</u> Diabetes Type 2	Initial Entry

*1.f Start Date:*

Date	Location	User	Value	Reason
Oct-15-2020 12:59:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<u>Data Entry:</u> UNK/UNK/2000	Initial Entry

*1.f Ongoing:*

Date	Location	User	Value	Reason
Oct-15-2020 12:59:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<u>Data Entry:</u> YES	Initial Entry

*1.g*

Date	Location	User	Value	Reason
Oct-15-2020 13:01:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Number 7 : Medical History T BPH erm: Start Date: UNK/UNK/2 019 Ongoing: YES	Initial Entry

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Generated By: (b) (4)

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**I.g Line/MH Number:**

Date	Location	User	Value	Reason
Oct-15-2020 13:01:07 (UTC-07:00) Mountain 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
Oct-15-2020 13:01:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<u>Data Entry:</u> BPH	Initial Entry

**I.g Start Date:**

Date	Location	User	Value	Reason
Oct-15-2020 13:01:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<u>Data Entry:</u> UNK/UNK/2019	Initial Entry

**I.g Ongoing:**

Date	Location	User	Value	Reason
Oct-15-2020 13:01:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<u>Data Entry:</u> YES	Initial Entry

**I.h**

Date	Location	User	Value	Reason
Oct-15-2020 13:03:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<u>Data Entry:</u> Line/MH Number: Medical History Kidney Stones Term: Start Date: UNK/UNK/2004	Transcription Error

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**Header Text:** C4591001

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**Site No:** 1221

**Subject No:** 12211002

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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			<b>Ongoing:</b> NO End Date:  Oct/UNK/ 2019	
Oct-15-2020 13:01:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 8 <b>Medical History Term:</b> Kidney Stones <b>Start Date:</b> UNK/UNK/2004 <b>Ongoing:</b> NO End Date:  Oct/UNK/ 2020	Initial Entry

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Generated By: (b) (4)

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**I.h Line/MH Number:**

Date	Location	User	Value	Reason
Oct-15-2020 13:01:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 8	Initial Entry

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

Date	Location	User	Value	Reason
Oct-15-2020 13:01:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Kidney Stones	Initial Entry

**I.h Start Date:**

Date	Location	User	Value	Reason
Oct-15-2020 13:01:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> UNK/UNK/2004	Initial Entry

**I.h Ongoing:**

Date	Location	User	Value	Reason
Oct-15-2020 13:03:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> NO End Date:  Oct/UNK/2019	Transcription Error
Oct-15-2020 13:01:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> NO End Date:  Oct/UNK/2020	Initial Entry

**I.i**

Date	Location	User	Value	Reason
Oct-15-2020 13:04:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Num 9 ber:	Initial Entry

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**Site No:** 1221

**Subject No:** 12211002

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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			<b>Medical History Term:</b>	Congesutive Heart Failure	
			<b>Start Date:</b>	Jul/UNK/2019	
			<b>Ongoing:</b>	YES	



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Subject No: 12211002

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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***1.i Line/MH Number:***

Date	Location	User	Value	Reason
Oct-15-2020 13:04:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 9	Initial Entry

***1.i Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Oct-15-2020 13:04:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Congesutive Heart Failure	Initial Entry

***1.i Start Date:***

Date	Location	User	Value	Reason
Oct-15-2020 13:04:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Jul/UNK/2019	Initial Entry

***1.i Ongoing:***

Date	Location	User	Value	Reason
Oct-15-2020 13:04:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> YES	Initial Entry

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Header Text: C4591001

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Site No: 1221

Subject No: 12211002

Generated By: (b) (4)

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**1. Date:**

Date	Location	User	Value	Reason
Oct-15-2020 13:16:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Oct/13/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Oct-18-2020 23:57:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Response satisfies query.
Oct-18-2020 14:38:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Answered	Original value is correct
Oct-15-2020 23:47:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2: Closed	Another query raised for the same
Oct-15-2020 23:47:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Reissued:Opened	DM: Thanks for the response. Please review the value and confirm if it is clinically significant or not.
Oct-15-2020 13:34:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Query 2: Answered	Original value is correct
Oct-15-2020 13:34:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Weight 307.4 is outside of Normal Range 25 - 136 for kg or 50 - 300 for lb.
Oct-15-2020 13:34:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> 307.4	Transcription Error
Oct-15-2020 13:33:59	ACV0PFEINFP6000	Jane Halpern	Query 1: Answered	Original value is

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Subject No: 12211002

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

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(UTC-07:00) Mountain Time (US & Canada)		(b) (4)		correct
Oct-15-2020 13:33:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Weight 307 is outside of Normal Range 25 - 136 for kg or 50 - 300 for lb.
Oct-15-2020 13:33:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> 307.0	Wt. rounded down to 307 lb.
Oct-15-2020 13:16:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Weight 307.4 is outside of Normal Range 25 - 136 for kg or 50 - 300 for lb.
Oct-15-2020 13:16:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> 307.4	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Oct-15-2020 13:16:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Oct-15-2020 13:16:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> 73.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Oct-15-2020 13:16:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> in	Initial Entry

6. Body Mass Index:

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Generated By: (b) (4)

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Date	Location	User	Value	Reason
Oct-15-2020 13:34:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 40.6	Transcription Error
Oct-15-2020 13:33:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 40.5	Wt. rounded down to 307 lb.
Oct-15-2020 13:16:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 40.6	Initial Entry

7.a

Date	Location	User	Value	Reason
Oct-15-2020 13:16:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<u>Data Entry:</u> Record Identifier:: 1 Temperature: 98.7 Temperature Unit: F Temperature Locat ion:: FOREHE AD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Oct-15-2020 13:16:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<u>Data Entry:</u> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Oct-15-2020 13:16:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<u>Data Entry:</u> 98.7	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Oct-15-2020 13:16:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<u>Data Entry:</u> F	Initial Entry

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**Header Text:** C4591001

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**Site No:** 1221

**Subject No:** 12211002

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

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**7.a Temperature Location:**

Date	Location	User	Value	Reason
Oct-15-2020 13:16:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> FOREHEAD	Initial Entry

**Header Text:** C4591001

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** RANDOMIZATION - eCRF Audit Trail History

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Oct-15-2020 13:17:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Oct/13/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Oct-15-2020 13:17:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> 107094	Initial Entry

Header Text: C4591001

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-15-2020 13:20:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-15-2020 13:20:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-15-2020 13:21:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-15-2020 13:20:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-15-2020 13:20:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Oct/13/2020	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Nov-09-2020 04:49:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	issue resolved

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**Header Text:** C4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1221**Site Name:** (1221) Center for American Indian Health - Gallup**Subject No:** 12211002**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11

Nov-05-2020 03:43:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Reissued:Candidate	Issue is still present will wait for latest report.
Nov-04-2020 10:05:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Answered	Sera sample entered.
Nov-03-2020 07:21:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Reissued:Opened	HOLDS: Please submit an updated SCF and confirm submission.
Nov-02-2020 17:10:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Answered	Sample was sent to lab & documented on original SCF. This sample was entered, staff error. Attempting to unfreeze data so sample can be enter. Will another SCF need to sent? Please advise or unfreeze data. Thank you.
Nov-01-2020 22:30:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Query 1: Opened	HOLDS: Serum barcode BS71YH was received by the lab for Visit 1. Please submit an updated SCF and confirm submission.

**5.a**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-15-2020 13:23:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BR8BP0	Changed Information
Oct-15-2020 13:21:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b> BR8BNZ	Initial Entry



Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.a Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 13:23:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<u>Data Entry:</u> BR8BP0	Changed Information
Oct-15-2020 13:21:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<u>Data Entry:</u> BR8BNZ	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-15-2020 13:26:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<u>Data Entry:</u> Sample ID: BS71YG	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 13:26:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<u>Data Entry:</u> BS71YG	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-04-2020 10:02:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Sample ID: BS71YH	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-04-2020 10:02:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> BS71YH	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-15-2020 13:28:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-15-2020 13:28:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-15-2020 13:38:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-15-2020 13:28:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-15-2020 13:28:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Oct/13/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-15-2020 13:38:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Sample ID: BR8BNZ	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-15-2020 13:38:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> BR8BNZ	Initial Entry

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1221

Subject No: 12211002

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Oct-15-2020 13:32:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Oct-15-2020 13:32:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Oct-15-2020 13:32:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Oct-15-2020 13:32:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Oct/13/2020 11:44	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Oct-15-2020 13:32:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Oct-15-2020 13:32:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> LEFT	Initial Entry

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**Header Text:** C4591001

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

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** VACCINATION - eCRF Audit Trail History

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

Time (US & Canada)				
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**7. Route:**

Date	Location	User	Value	Reason
Oct-15-2020 13:32:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Oct-15-2020 13:32:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED O BSERVATION 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
Oct-15-2020 13:32:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Oct-15-2020 13:32:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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*1. Date of Visit*

Date	Location	User	Value	Reason
Nov-02-2020 12:48:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Gwen Livingston (b) (4)	<b>Data Entry:</b> Nov/2/2020	Initial Entry

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 10-Oct-2020 16:01

Site No: 1221

Subject No: 12211002

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Date:**

Date	Location	User	Value	Reason
Nov-02-2020 12:49:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Gwen Livingston (b) (4)	<b>Data Entry:</b> Nov/2/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Nov-02-2020 12:49:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Gwen Livingston (b) (4)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 : <b>Temperature:</b> 96.4 <b>Temperature Unit</b> F : <b>Temperature Location:</b> FOREHEAD	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Nov-02-2020 12:49:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Gwen Livingston (b) (4)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Nov-03-2020 04:45:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 1: Closed	Response satisfies query
Nov-02-2020 13:30:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	Original value is correct
Nov-02-2020 12:49:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 96.4 F is outside of Normal Range 97 - 99.5 F.

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**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

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**Site Name:** (1221) Center for American Indian Health - Gallup

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Nov-02-2020 12:49:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Gwen Livingston (b) (4)	<b>Data Entry:</b> 96.4	Initial Entry
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**2.a Unit:**

Date	Location	User	Value	Reason
Nov-02-2020 12:49:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Gwen Livingston (b) (4)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Nov-02-2020 12:49:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Gwen Livingston (b) (4)	<b>Data Entry:</b> FOREHEAD	Initial Entry

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Header Text: C4591001

Visit: V2\_VAX2\_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Data Origin**

Date	Location	User	Value	Reason
Nov-02-2020 12:58:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-02-2020 12:58:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-17-2020 13:34:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 4: Closed	Response satisfies query
Nov-17-2020 11:29:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 4: Answered	Changed data per query
Nov-13-2020 20:59:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 4: Reissued:Opened	DM: Please mark Not Applicable under field #5.a. Thank you.
Nov-13-2020 17:59:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 4: Answered	Nasal sample that was collected was moved to COVID illness sample.
Nov-13-2020 17:58:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (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:** 1221**Site Name:** (1221) Center for American Indian Health - Gallup**Subject No:** 12211002**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11

				provide reason' is missing. Please review and update as appropriate.
Nov-13-2020 17:58:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Nov-13-2020 17:58:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> NO	Nasal sample collected was used for COVID illness event
Nov-12-2020 16:00:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 3: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-12-2020 14:20:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-11-2020 00:43:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Closed	Response satisfies query
Nov-09-2020 20:38:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Query 2: Answered	V2 was completed on 2/Nov/2020, including sample collections. Covid Illness visit was televisit on 3 Nov., after subject was admitted to the hospital with positive COVID test.
Nov-08-2020 14:22:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Opened	Clin: Visit-2 occurred at the same time as a

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
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**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

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

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				COVID Illness visit, sample collection date and barcodes should be recorded on the Electronic Sample Tracking – Nasal Swab under the Illness visit only since the SELF_SWAB was not collected.
Nov-02-2020 13:36:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-02-2020 12:58:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-02-2020 12:58:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Gwen Livingston (b) (4)	<b>Data Entry:</b> YES Date of Collection:  Nov/2/2020	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Nov-17-2020 11:27:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-12-2020 14:20:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> <b>Sample ID:</b>	Changed Information
Nov-02-2020 13:36:11	ACV0PFEINFP6000	(b) (6)	<b>Data Entry:</b>	Initial Entry

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(UTC-07:00) Mountain  
Time (US & Canada)

(b) (4)

Sample ID: BR8BR7

5.a Sample ID

Date	Location	User	Value	Reason
Nov-12-2020 19:42:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Clo sed	Auto closed by Validation Check: VC_BEETRK001_01
Nov-12-2020 14:20:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swere d	Changed Information
Nov-12-2020 14:20:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry</b> :	Changed Information
Nov-12-2020 01:53:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Query 1: Rei ssued: Opene d	DM: Barcode BR8BR7 is recorded at COVID_A visit also. Please review and amend the duplicate data as appropriate else clarify.
Nov-11-2020 08:11:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: An swere d	Yes. Nasal swap was also recorded for this event.
Nov-11-2020 02:14:49 (UTC-07:00)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW5351445;This Barcode is already recorded more than

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**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
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**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

Mountain Time (US & Canada)				once (for the same subject). Please review and update as appropriate.
Nov-02-2020 13:36:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry</b> : BR8B R7	Initial Entry

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1221

Subject No: 12211002

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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**I. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Nov-17-2020 13:34:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Closed	Response satisfies query
Nov-17-2020 11:33:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	Verified that symptoms start date is 01 Nov 2020. Confirmed with Study MD.
Nov-13-2020 08:15:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Reissued:Opened	CLIQUEY: in this case, please clarify, if the symptoms start date in the illness visit SOD CRF should be updated.
Nov-12-2020 14:19:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Query 1: Answered	At Day of V2, patient denied any symptoms at time of visit. His symptom of prior day had resolved. So Dose2 was not delayed. He developed COVID symptoms later that evening of v2.
Nov-12-2020 06:26:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Opened	CLIQUEY: date of 1st symptom started is day before the subject received VAX#2. Please clarify if temporary delay of vaccination criteria were assessed?
Nov-02-2020 13:03:46 (UTC-07:00) Mountain	ACV0PFEINFP6000	Gwen Livingston	<b>Data Entry:</b> NO	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1221

Subject No: 12211002

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Time (US & Canada)	(b) (4)
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2. Treatment Name

Date	Location	User	Value	Reason
Nov-02-2020 13:03:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Nov-02-2020 13:03:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Nov-02-2020 13:03:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Gwen Livingston (b) (4)	<u>Data Entry:</u> Nov/2/2020 09:52	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Nov-02-2020 13:03:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Nov-02-2020 13:03:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Gwen Livingston (b) (4)	<u>Data Entry:</u> LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Nov-02-2020 13:03:46 (UTC-07:00) Mountain	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)



**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** VACCINATION - eCRF Audit Trail History

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

Time (US & Canada)				
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**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Nov-02-2020 13:03:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED O BSERVATION 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
Nov-02-2020 13:03:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Gwen Livingston (b) (4)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1221

**Subject No:** 12211002

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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*1. Date of Visit*

Date	Location	User	Value	Reason
Dec-04-2020 12:04:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Dec/4/2020	Initial Entry

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: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Data Origin**

Date	Location	User	Value	Reason
Dec-04-2020 12:07:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-04-2020 12:07:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-04-2020 12:08:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-04-2020 12:07:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-04-2020 12:07:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> YES Date of Collection: Dec/4/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-04-2020 12:08:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Sample ID: BR8BX9	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.a Sample ID

Date	Location	User	Value	Reason
Dec-04-2020 12:08:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> BR8BX9	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-04-2020 12:19:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Sample ID:</b> BS723Y	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-04-2020 12:19:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> BS723Y	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-04-2020 12:19:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Sample ID:</b> BS723Z	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-04-2020 12:19:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> BS723Z	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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*I. Date of Visit*

Date	Location	User	Value	Reason
Nov-12-2020 23:46:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Response satisfies query
Nov-12-2020 14:35:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query
Nov-11-2020 02:37:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Reissued:Opened	DM1: Thank you for response. Nasal swab at this visit is completed. However, data is missing in Nasal self swab form. Please review and update data accordingly.
Nov-10-2020 14:44:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Query 1: Answered	Subject discharged from hosp. to hotel on Nov.6. Trying to contact him to get an illness swab. Have left msg. but hasn't responded yet.
Nov-06-2020 00:08:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Reissued:Opened	DM: Thank you for the response. Please update Nasal Swab Self and Nasal Swab forms providing the same reason given in previous query response.
Nov-05-2020 09:21:53 (UTC-07:00) Mountain	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	Query 1: Answered	Visit was by telephone. As

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

Time (US & Canada)				subject was in an Emergency Room, and then subsequently admitted, neither us or the subject has had a chance to obtain the sample.
Nov-04-2020 01:14:42 (UTC-07:00) Mountain 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-03-2020 11:27:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Nov-03-2020 11:26:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Nov-03-2020 11:26:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Nov-03-2020 11:26:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> Nov/3/2020	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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

Date	Location	User	Value	Reason
Nov-03-2020 11:26:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> COVID_A	Initial Entry

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Nov-03-2020 11:27:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> Nov/3/2020	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Nov-17-2020 13:35:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Closed	Response satisfies query
Nov-17-2020 11:37:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Answered	First symptom (Nasal Congestion) occurred on 01 Nov 2020. Resolved prior vaccination #2 on 02 Nov 2020. Symptoms resumed post vaccination. Study MD confirmed that COVID symptoms started on 01 Nov 2020.
Nov-13-2020 20:07:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Opened	CLINQUERY: Query response on V2 indicate that the subject develop symptoms after vax2 date, please review and clarify as appropriate.
Nov-13-2020 08:14:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Candidate	CLINQUERY: Query response on V2 indicate that the subject develop symptoms after

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

				vax2 date, please review and clarify as appropriate.
Nov-03-2020 11:27:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> Nov/1/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Jan-08-2021 06:51:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Response satisfies query
Jan-07-2021 17:50:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Jan-07-2021 17:50:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> NO Date of Last Symptom Resolved:  Nov/20/2020	Changed Information
Jan-07-2021 14:45:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Opened	CLINQUERY: Please clarify whether the reported symptoms are still ongoing? If symptoms have ended, please update 'Symptoms Ongoing' on to 'NO' and add Date of Last Symptom Resolved on the CRF.
Nov-03-2020 11:27:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> YES	Initial Entry

4.a

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Date	Location	User	Value	Reason
Nov-03-2020 11:27:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan Vanderiet (b) (4)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b> NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 11:27:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan Vanderiet (b) (4)	<b>Data Entry:</b> FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 11:27:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan Vanderiet (b) (4)	<b>Data Entry:</b> NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Nov-03-2020 11:27:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan Vanderiet (b) (4)	<b>Data Entry:</b> <b>Symptoms</b> NEW OR INCRE : ASED COUGH <b>Symptom</b> NO <b>Present:</b>	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1221**Site Name:** (1221) Center for American Indian Health - Gallup**Subject No:** 12211002**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11**4.b Symptoms:**

Date	Location	User	Value	Reason
Nov-03-2020 11:27:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> NEW OR INCREASED COUGH	Initial Entry

**4.b Was symptom present?**

Date	Location	User	Value	Reason
Nov-03-2020 11:27:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**4.c**

Date	Location	User	Value	Reason
Nov-03-2020 11:27:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> <b>Symptom:</b> NEW OR INCREASED SHORTNESS OF BREATH <b>Symptom Present:</b> NO	Initial Entry

**4.c Symptoms:**

Date	Location	User	Value	Reason
Nov-03-2020 11:27:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

**4.c Was symptom present?**

Date	Location	User	Value	Reason
Nov-03-2020 11:27:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**4.d**

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Nov-03-2020 11:27:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS <b>Symptom Present:</b> YES	Initial Entry
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4.d Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 11:27:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 11:27:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> YES	Initial Entry

4.e

Date	Location	User	Value	Reason
Nov-03-2020 11:27:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> <b>Symptom</b> NEW OR INCREA SED MUSCLE PAI N <b>Symptom NO</b> <b>Present:</b>	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 11:27:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> NEW OR INCREASED MUSC LE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 11:27:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

4.f

Date	Location	User	Value	Reason
Nov-03-2020 11:27:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> <b>Symptom</b> NEW LOSS OF TASTE OR SMELL <b>Symptom</b> NO <b>Present:</b>	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Nov-03-2020 11:27:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Nov-03-2020 11:27:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Nov-03-2020 11:27:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> <b>Symptom</b> NEW OR INCREASED SORE THROAT <b>Symptom</b> NO <b>Present:</b>	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1221**Site Name:** (1221) Center for American Indian Health - Gallup**Subject No:** 12211002**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11**4.g Symptoms:**

Date	Location	User	Value	Reason
Nov-03-2020 11:27:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> NEW OR INCREASED SORE THROAT	Initial Entry

**4.g Was symptom present?**

Date	Location	User	Value	Reason
Nov-03-2020 11:27:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**4.h**

Date	Location	User	Value	Reason
Nov-03-2020 11:27:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> <b>Symptoms:</b> DIARRHEA A <b>Symptom Present:</b> NO	Initial Entry

**4.h Symptoms:**

Date	Location	User	Value	Reason
Nov-03-2020 11:27:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> DIARRHEA	Initial Entry

**4.h Was symptom present?**

Date	Location	User	Value	Reason
Nov-03-2020 11:27:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**4.i**

Date	Location	User	Value	Reason
Nov-03-2020 11:27:49	ACV0PFEINFP6000	Dan VandeRiet	<b>Data Entry:</b>	Initial Entry

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

(UTC-07:00) Mountain Time (US & Canada)		(b) (4)	<b>Symptoms:</b> VOMITIN G <b>Symptom Present:</b> YES	
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**4.i Symptoms:**

Date	Location	User	Value	Reason
Nov-03-2020 11:27:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan Vanderiet (b) (4)	<b>Data Entry:</b> VOMITING	Initial Entry

**4.i Was symptom present?**

Date	Location	User	Value	Reason
Nov-03-2020 11:27:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan Vanderiet (b) (4)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail  
on Nov/03/2020

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

**Form Status:**

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Date	Location	User	Value	Reason
Nov-12-2020 14:30:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Form Created	



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Nov/03/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Nov-12-2020 14:46:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Closed	Response satisfies query
Nov-12-2020 14:30:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Nov-12-2020 14:30:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Nov/3/2020	Initial Entry
Nov-11-2020 03:46:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Reissued:Opened	CLIQUEY: Please respond to discrepancy once information is available to add to CRF.
Nov-10-2020 16:22:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Reissued:Candidate	CLIQUEY: Please respond to discrepancy once information is available to add to CRF.
Nov-10-2020 14:40:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Query 1: Answered	pt. hospitalized Nov.3-6 so unable to obtain illness nasal swab. Discharged Nov. 6 to hotel and are trying to contact him to obtain illness sample.
Nov-09-2020 01:34:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Query 1: Opened	CLIQUEY: Please complete required CRF.
Nov-06-2020 11:55:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (6)	Query 1: Candidate	CLIQUEY: Please complete required

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Nov/03/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Time (US & Canada)	(b) (4)	CRF.
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2. Specimen Type:

Date	Location	User	Value	Reason
Nov-13-2020 09:56:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Closed	Response satisfies query
Nov-12-2020 14:30:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Nov-12-2020 14:30:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> SWABBED MATERIAL	Initial Entry
Nov-11-2020 03:11:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Opened	DM: Please update data on this form else mark as Not done by adding reason why assessment was not done. Thank you.

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Nov-12-2020 14:30:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Nov-12-2020 14:30:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RESP SYNDR OME CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Nov-12-2020 14:30:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGNOSTIC TES	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

Time (US & Canada)			T	
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**6. Trade Name:**

Date	Location	User	Value	Reason
Nov-12-2020 14:30:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> ABBOTT MOLECULAR REAL TIME SARS-COV-2 ASSAY	Initial Entry

**7. Test Result:**

Date	Location	User	Value	Reason
Nov-12-2020 14:30:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> POSITIVE	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020**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:** 1221**Site Name:** (1221) Center for American Indian Health - Gallup**Subject No:** 12211002**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-12-2020 14:35:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-12-2020 14:35:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-12-2020 14:35:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Nov-12-2020 14:35:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Patient in hospital on 3 Nov. and was unable to do self swab.	Initial Entry

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020**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:** 1221**Site Name:** (1221) Center for American Indian Health - Gallup**Subject No:** 12211002**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-10-2020 19:37:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-10-2020 19:37:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-12-2020 23:04:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2: Closed	Response satisfies query
Nov-12-2020 14:33:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Query 2: Answered	Confirm Nov. 2; since patient hospitalized on Nov. 3 with COVID-19, monitor advised us to enter V2 nasal swab on COVID illness crf, since it was positive.
Nov-12-2020 07:49:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2: Reissued:Opened	Please review and confirm date of collection is correct as entered as it is different from Date of visit at this visit or else clarify.
Nov-11-2020 00:43:02 (UTC-07:00) Mountain	ACV0PFEINFP6000	Salim Bouguermouh	Query 1: Closed	Response satisfies query

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020**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:** 1221**Site Name:** (1221) Center for American Indian Health - Gallup**Subject No:** 12211002**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11

Time (US & Canada)		(b) (4)		
Nov-10-2020 19:40:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2: Answered	Original value is correct
Nov-10-2020 19:39:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query
Nov-10-2020 19:37:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-10-2020 19:37:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Date of Collection 02/Nov/2020 is different from Date of Visit 03/Nov /2020. Please review and update as appropriate, else clarify.
Nov-10-2020 19:37:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Nov-10-2020 19:37:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> YES Date of Collection:  Nov/2/2020	Initial Entry
Nov-08-2020 14:21:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Visit-2 occured at the same time as a COVID Illness visit, sample collection date and barcodes should be recorded on the Electronic Sample Tracking – Nasal Swab under the Illness visit only

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020**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:** 1221**Site Name:** (1221) Center for American Indian Health - Gallup**Subject No:** 12211002**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11

since the SELF\_SWAB was not collected.

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Dec-02-2020 06:05:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b)(6)	Query 1: Closed	Response satisfies query
Nov-30-2020 11:28:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	Nasal swab collected on November 2, 2020 for this visit
Nov-29-2020 08:58:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Opened	ClinQuery: sample was moved from V2 to illness visit. Please review comment and update as needed as bar code was entered at this visit.
Nov-12-2020 14:32:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Collected at V2, Nov.2 because patient admitted to hospital on Nov.3 with COVID-19 pneumonia . No self or site nasal swab collected on Nov. 3 illness visit, which was a televisit.	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-10-2020 19:39:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Sample ID:</b> BR8BR7	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Nov-12-2020	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY	Query	Auto closed by

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020**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:** 1221**Site Name:** (1221) Center for American Indian Health - Gallup**Subject No:** 12211002**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11

19:42:37 (UTC-07:00) Mountain Time (US & Canada)		(b) (4)	1: Clo sed	Validation Check: VC_BEETRK001_01
Nov-12-2020 14:33:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Query 1: An swere d	Changed data per query
Nov-12-2020 04:15:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Query 1: Rei ssued: Opene d	DM: Barcode BR8BR7 is recorded at V2VX2L visit also. Please review and amend the duplicate data as appropriate else clarify.
Nov-11-2020 08:12:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: An swere d	Yes, nasal sample was also recorded for this event
Nov-11-2020 02:14:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW5351444;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Nov-10-2020 19:39:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry</b> : BR8B R7	Initial Entry



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/03/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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*1.a*

Date	Location	User	Value	Reason
Nov-03-2020 11:39:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> Type of Practitioner : SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

*1.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Nov-03-2020 11:39:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> SPECIALIST	Initial Entry

*1.a Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Nov-03-2020 11:39:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> NO	Initial Entry

*1.b*

Date	Location	User	Value	Reason
Nov-03-2020 11:39:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: YES Number of Visits or Contacts: 1	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/03/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1221**Site Name:** (1221) Center for American Indian Health - Gallup**Subject No:** 12211002**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11***I.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-03-2020 11:39:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

***I.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-03-2020 11:39:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> YES <i>Number of Visits or Contacts:</i>  1	Initial Entry

***I.c***

Date	Location	User	Value	Reason
Nov-03-2020 11:39:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> <b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

***I.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-03-2020 11:39:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

***I.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-03-2020 11:39:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> NO	Initial Entry

***I.d***

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/03/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Date	Location	User	Value	Reason
Nov-03-2020 11:39:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan Vanderiet (b) (4)	<b>Data Entry:</b> <b>Type of Practitioner:</b> URGENT CARE <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

*I.d Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Nov-03-2020 11:39:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan Vanderiet (b) (4)	<b>Data Entry:</b> URGENT CARE	Initial Entry

*I.d Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Nov-03-2020 11:39:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan Vanderiet (b) (4)	<b>Data Entry:</b> NO	Initial Entry

*I.e*

Date	Location	User	Value	Reason
Nov-03-2020 11:39:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan Vanderiet (b) (4)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE CONSULTATION <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/03/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1221**Site Name:** (1221) Center for American Indian Health - Gallup**Subject No:** 12211002**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-03-2020 11:39:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> TELEPHONE CONSULTATIO N	Initial Entry

***1.e Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-03-2020 11:39:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> NO	Initial Entry

***1.f***

Date	Location	User	Value	Reason
Nov-03-2020 11:39:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTH ER <b>Occurrence of Visits or NO Contacts:</b>	Initial Entry

***1.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-03-2020 11:39:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> OTHER	Initial Entry

***1.f Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-03-2020 11:39:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> NO	Initial Entry

***3. Has the subject been hospitalized due to potential COVID-19 illness?***

Date	Location	User	Value	Reason
Nov-03-2020 11:39:53	ACV0PFEINFP6000	Dan VandeRiet	<b>Data Entry:</b>	Initial Entry

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

(UTC-07:00) Mountain Time (US & Canada)		(b) (4)	YES Has the subject been in intensive care due to potential COVID-19 illness?  NO	
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - Audit Trail  
on Nov/03/2020

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

**Form Status:**

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Date	Location	User	Value	Reason
Nov-03-2020 11:40:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	Form Created	

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History on Nov/03/2020

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Hospitalization Category:**

Date	Location	User	Value	Reason
Nov-03-2020 11:40:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> HOSPITALIZATION STATUS	Initial Entry

**2. Hospitalization Term:**

Date	Location	User	Value	Reason
Nov-03-2020 11:40:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan Vanderiet (b) (4)	<b>Data Entry:</b> HOSPITAL	Initial Entry

**3. Admission Date:**

Date	Location	User	Value	Reason
Nov-12-2020 14:47:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Response satisfies query
Nov-12-2020 14:34:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Query 1: Answered	Confirm that RESP Tx, Oxygen and Vasopress had no data, so Not applicable is correct.
Nov-11-2020 23:39:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Reissued:Opened	CLIQUEY: Please confirm there is no data for RESP TX, OXYGEN, VASOPRESS as Not applicable is entered?
Nov-11-2020 11:43:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Reissued:Candidate	CLIQUEY: Please confirm there is no data for RESP TX, OXYGEN, VASOPRESS as Not applicable is entered?

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - eCRF Audit Trail History on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

Nov-11-2020 09:27:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Query 1: Answered	Changed data per query
Nov-11-2020 03:06:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Reissued:Opened	CLIQUEY: Thanks for the response, however no data has been changed. Please provide missing CRF information on RESP TX, OXYGEN, VASOPRESS.
Nov-10-2020 06:03:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Reissued:Candidate	CLIQUEY: Hospitalization: This subject had COVID-19 Illness and was hospitalized. Please enter any available information (RESP TX, OXYGEN, VASOPRESS...). Please make every effort to obtain these information.
Nov-09-2020 19:40:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	Changed data per query
Nov-09-2020 01:37:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	Query 1: Opened	CLIQUEY: Hospitalization: This subject had COVID-19 Illness and was hospitalized. Please enter any available information (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...). Please make every effort to obtain these

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - eCRF Audit Trail History on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

				information.
Nov-06-2020 11:57:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Candidate	CLIQUERY: Hospitalization: This subject had COVID-19 Illness and was hospitalized. Please enter any available information (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...). Please make every effort to obtain these information.
Nov-03-2020 11:40:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> Nov/3/2020	Initial Entry

**4. Ongoing?**

Date	Location	User	Value	Reason
Nov-17-2020 13:30:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Response satisfies query
Nov-17-2020 11:38:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	Awaiting final discharge medical records
Nov-16-2020 12:38:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Opened	Please provide discharge date in source.
Nov-11-2020 09:39:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> NO Discharge Date: Nov/6/2020	New Information
Nov-03-2020 11:40:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> YES	Initial Entry

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: RESPIRATORY TREATMENT - eCRF Audit Trail History on Nov/03/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. What is the treatment Identifier?**

Date	Location	User	Value	Reason
Nov-11-2020 08:25:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Concomitant Non-drug Treatment Pre-specified:**

Date	Location	User	Value	Reason
Nov-11-2020 08:25:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Treatment:**

Date	Location	User	Value	Reason
Nov-13-2020 22:54:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Closed	Response satisfies query
Nov-12-2020 14:21:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Query 1: Answered	No, just clarifying that subject received low flow, not high flow O2 by nasal canula.
Nov-12-2020 02:35:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Opened	DM: Please confirm if Comment entered needs to be recorded in appropriate data point. Please confirm and correct else clarify, thank you.
Nov-11-2020 08:25:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

**4. Treatment:**

Date	Location	User	Value	Reason
Nov-11-2020 08:25:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Nov-11-2020 08:25:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Ongoing?**

Date	Location	User	Value	Reason
Nov-11-2020 08:25:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - eCRF Audit Trail History on Nov/03/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Nov-09-2020 18:43:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID-19 ILLNES S	Initial Entry

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

Date	Location	User	Value	Reason
Nov-12-2020 14:47:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 2: Closed	Response satisfies query
Nov-12-2020 14:23:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Query 2: Answered	Local test done at time of hospitalization for COVID19. Will record it on CRF.
Nov-11-2020 23:14:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Opened	Clinical Query: COVID-19 diagnosis should not be entered on this CRF unless there was a local positive test and symptoms recorded. As no local positive test recorded in COVID TEST CRF, please clarify or update.
Nov-11-2020 08:34:32	ACV0PFEINFP6000	(b) (6)	Query 2: Candidate	Clinical Query: COVID-19

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History  
on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

(UTC-07:00) Mountain Time (US & Canada)		(b) (4)		diagnosis should not be entered on this CRF unless there was a local positive test and symptoms recorded. As no local positive test recorded in COVID TEST CRF, please clarify or update.
Nov-11-2020 08:27:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnosis:</i>  Viral Pneumonia secondary to COVID-19  Date of Diagnosis:  Nov/3/2020	New Information
Nov-11-2020 03:36:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Nov-10-2020 14:45:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-10-2020 14:45:47	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> YES	Changed Information

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History  
on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

(UTC-07:00) Mountain Time (US & Canada)			<i>Respiratory Illness Diag nosis:</i>  Acute Viral Syndrome (COVID-1 9 POSITIV E)  Date of Diag nosis:  Nov/3/202 0	
Nov-10-2020 02:10:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Ope ned	Clarify ACUTE VIRAL SYNDROME (COVID POSITIVE) as follows...The term appears incomplete. Are you reporting ACUTE VIRAL SYNDROME (COVID-19 POSITIVE)? If so, update the verbatim term as such. Otherwise clarify and edit the term. Thank you.
Nov-09-2020 18:43:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> YES <i>Respiratory Illness Diag nosis:</i>  Acute Viral Syndrome (COVID P	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History  
on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

			ositive)	
			Date of Diag nosis:	
			Nov/3/202 0	

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Nov-09-2020 18:43:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> 3	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Nov-11-2020 09:32:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Subcategory of Clinical Event:**

Date	Location	User	Value	Reason
Nov-11-2020 09:37:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Was a diagnosis obtained?**

Date	Location	User	Value	Reason
Nov-11-2020 09:37:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Toxicity Grade:**

Date	Location	User	Value	Reason
Nov-11-2020 09:37:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

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

**Form Version:** 10-Oct-2020 15:58

**Form Status:**

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Date	Location	User	Value	Reason
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Form Created	

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> CLINICAL CHEMISTRY	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Rehoboth McKinley Christian Hospital, 1901 Red Rock Dr, Gallup NM 87301	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Nov/3/2020	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLOOD	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-09-2020 18:51:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Sponsor-Define 329 <b>d Identifier:</b> <b>Test::</b> C Reactive Protein_PX329 <b>Result::</b> <0.5 <b>Not Done::</b>	New Information

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

			<b>Lab Normal Range:</b> <i>Low</i> 0.0  <i>High</i> 0.5  <i>Unit</i> mg/dL	
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 329 <b>Test::</b> C Reactive Protein_PX329 <b>Result::</b> <0.5 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Unit</i> mg/dL	Initial Entry

**5.a Sponsor ID:**

Date	Location	User	Value	Reason
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 329	Initial Entry

**5.a Test:**

Date	Location	User	Value	Reason
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> C Reactive Protein_PX329	Initial Entry

**5.a Result:**

Date	Location	User	Value	Reason
Nov-09-2020 18:51:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

				Unit) is missing. Please correct or confirm.
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <0.5	Initial Entry

**5.a LNMT**

Date	Location	User	Value	Reason
Nov-09-2020 18:51:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <i>Low</i> 0.0  <i>High</i> 0.5  <i>Unit</i> mg/dL	New Information
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <i>Unit</i> mg/dL	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Nov-09-2020 18:52:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Alanine Aminotransferase_PX30 <b>Result::</b> 50 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0  <i>High</i> 50  <i>Unit</i> U/L	New Information

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocale)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 30 <b>Test::</b> Alanine Aminotransferase_PX30 <b>Result::</b> 50 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Unit</i> U/L	Initial Entry
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30	Initial Entry

**5.b Test:**

Date	Location	User	Value	Reason
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Alanine Aminotransferase_PX30	Initial Entry

**5.b Result:**

Date	Location	User	Value	Reason
Nov-09-2020 18:52:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> 50	Initial Entry

**5.b LNMT**

Date	Location	User	Value	Reason
Nov-09-2020 18:52:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Low 0  High 50  Unit	New Information

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

			U/L	
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <i>Unit</i> U/L	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-09-2020 18:52:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> : <b>Test::</b> Aspartate Aminotransferase_PX28 <b>Result::</b> 54 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 17  <i>High</i> 59  <i>Unit</i> U/L	New Information
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> : <b>Test::</b> Aspartate Aminotransferase_PX28 <b>Result::</b> 54 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Unit</i> U/L	Initial Entry

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**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:58**Form Status:** Data Complete, Frozen, Verified**Site No:** 1221**Site Name:** (1221) Center for American Indian Health - Gallup**Subject No:** 12211002**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 28	Initial Entry

**5.c Test:**

Date	Location	User	Value	Reason
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Aspartate Aminotransferase_PX28	Initial Entry

**5.c Result:**

Date	Location	User	Value	Reason
Nov-09-2020 18:52:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> 54	Initial Entry

**5.c LNMT**

Date	Location	User	Value	Reason
Nov-09-2020 18:52:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <i>Low</i> 17 <i>High</i> 59 <i>Unit</i>	New Information



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

			U/L	
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <i>Unit</i> U/L	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-09-2020 18:53:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Alkaline Phosphatase_PX35 <b>Result::</b> 140 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 38 <i>High</i> 126 <i>Unit</i> U/L	New Information
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Alkaline Phosphatase_PX35 <b>Result::</b> 140 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>High</i> Yes <i>Unit</i> U/L	Initial Entry

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.d Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 35	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Alkaline Phosphatase_PX35	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Nov-09-2020 18:53:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> 140	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Nov-09-2020 18:53:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Low 38  High 126  Unit	New Information

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

			U/L	
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <i>High</i> Yes  <i>Unit</i> U/L	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-09-2020 18:53:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 21 <b>Test::</b> Bilirubin_P X21 <b>Result::</b> 0.5 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0.2  <i>High</i> 1.3  <i>Unit</i> mg/dL	New Information
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 21 <b>Test::</b> Bilirubin_P X21 <b>Result::</b> 0.5 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Unit</i> mg/dL	Initial Entry

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.e Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 21	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Bilirubin_PX21	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Nov-09-2020 18:53:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> 0.5	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Nov-09-2020 18:53:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u>  Low 0.2  High 1.3  Unit	New Information

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

			mg/dL	
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <i>Unit</i> mg/dL	Initial Entry

5.f

Date	Location	User	Value	Reason
Nov-09-2020 18:53:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Blood Urea Nitrogen_PX47 <b>Result::</b> 11 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 9 <i>High</i> 20 <i>Unit</i> mg/dL	New Information
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Blood Urea Nitrogen_PX47 <b>Result::</b> 11 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Unit</i> mg/dL	Initial Entry

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

**5.f Sponsor ID:**

Date	Location	User	Value	Reason
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 47	Initial Entry

**5.f Test:**

Date	Location	User	Value	Reason
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Blood Urea Nitrogen_PX47	Initial Entry

**5.f Result:**

Date	Location	User	Value	Reason
Nov-09-2020 18:53:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

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5.f Result:

Date	Location	User	Value	Reason
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> 11	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Nov-09-2020 18:53:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <i>Low</i> 9  <i>High</i> 20  <i>Unit</i> mg/dL	New Information
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <i>Unit</i> mg/dL	Initial Entry

5.g

Date	Location	User	Value	Reason
Nov-09-2020 18:54:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Sponsor-Defined I</b> 48 <b>dentifier:</b> <b>Test::</b> Creatinine_ PX48 <b>Result::</b> 0.6 <b>Not Done::</b>	New Information

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

			<b>Lab Normal Range</b> <i>Low</i> :  <i>High</i> 1.3  <i>Unit</i> mg/dL	
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 48 <b>Test::</b> Creatinine_ PX48 <b>Result::</b> 0.6 <b>Not Done::</b> <b>Lab Normal Range</b> <i>Low</i> :  <i>Unit</i> mg/dL	Initial Entry

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.g Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 48	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Creatinine_PX48	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Nov-09-2020 18:54:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> 0.6	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Nov-09-2020 18:54:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u>  Low 0.7  High 1.3  Unit	New Information

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

			mg/dL	
Nov-09-2020 18:49:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <i>Low</i> Yes  <i>Unit</i> mg/dL	Initial Entry

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

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

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

**Form Status:**

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Form Created	

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> HEMATOLOGY	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Rehoboth McKinley Christian Hospital, 1901 Red Rock Dr, Gallup NM 87301	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Nov/3/2020	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLOOD	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 1 <b>Test::</b> Hemoglobin _PX1 <b>Result::</b> 16.1 <b>Not Done::</b>	Initial Entry

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

			<b>Lab Normal Range</b> <i>Low</i> : 14.0  <i>High</i> 18.0  <i>Unit</i> g/dL	
--	--	--	--	--

5.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Hemoglobin_PX1	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> 16.1	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <i>Low</i> 14.0  <i>High</i> 18.0  <i>Unit</i> g/dL	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

5.b

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Id 2 entifier:</b> <b>Test::</b> Hematocrit_ PX2 <b>Result::</b> 48.4 <b>Not Done::</b> <b>Lab Normal Range</b> <i>Low</i> : 41.0  <i>High</i> 49.0  <i>Unit</i> %	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.b Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 2	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Hematocrit_PX2	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> 48.4	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> <i>Low</i> 41.0  <i>High</i> 49.0  <i>Unit</i> %	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> <b>Sponsor-Defined I 3 identifier:</b> <b>Test::</b> Erythrocytes_PX3	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

			<b>Result::</b> 5.41	
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b> <i>Low</i> 4.00	
			<i>High</i> 5.60	
			<i>Unit</i> 10 <sup>6</sup> /cu m	
			m	



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

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Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.c Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Erythrocytes_PX3	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> 5.41	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b>  <i>Low</i> 4.00  <i>High</i> 5.60  <i>Unit</i> 10^6/cu mm	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Platelets_PX5	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

			<b>Result::</b> 198	
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b> <i>Low</i>	
			180	
			<i>High</i>	
			430	
			<i>Unit</i>	
			10 <sup>6</sup> /cu	
			mm	

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.d Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 5	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Platelets_PX5	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> 198	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> <i>Low</i> 180  <i>High</i> 430  <i>Unit</i> 10^6/cu mm	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> <b>Sponsor-Defined Id 7 entifier:</b> <b>Test::</b> Leukocytes_PX7	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

			<b>Result::</b> 5.70	
			<b>Not Done::</b>	
			<b>Lab Normal Range</b> <i>Low</i>	
			:	4.5
				<i>High</i>
				11.0
			<i>Unit</i>	
				10 <sup>6</sup> /cu m
				m

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.e Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 7	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Leukocytes_PX7	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> 5.70	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> <i>Low</i> 4.5  <i>High</i> 11.0  <i>Unit</i> 10^6/cu mm	Initial Entry

5.f

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> <b>Sponsor-Defined I 608 identifier:</b> <b>Test::</b> Neutrophils_PX608	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

			<b>Result::</b> 3.8	
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b> <i>Low</i>	
			1.5	
			<i>High</i>	
			8.0	
			<i>Unit</i>	
			10 <sup>6</sup> /cu mm	

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.f Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 608	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Neutrophils_PX608	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> 3.8	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> <i>Low</i> 1.5  <i>High</i> 8.0  <i>Unit</i> 10^6/cu mm	Initial Entry

5.g

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> <b>Sponsor-Defined I</b> 609 <b>dentifier:</b> <b>Test::</b> Eosinophils_ PX609	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

			<b>Result::</b> 0.0	
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b> <i>Low</i>	
			0.0	
			<i>High</i>	
			1.0	
			<i>Unit</i>	
			10 <sup>6</sup> /cu mm	



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

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Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.g Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 609	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Eosinophils_PX609	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> 0.0	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> <i>Low</i> 0.0  <i>High</i> 1.0  <i>Unit</i> 10^6/cu mm	Initial Entry

5.h

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> <b>Sponsor-Defined I</b> 612 <b>dentifier:</b> <b>Test::</b> Monocytes_P X612	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

			<b>Result::</b> 1.0	
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b> <i>Low</i>	
			0.0	
			<i>High</i>	
			1.0	
			<i>Unit</i>	
			10 <sup>6</sup> /cu m	
			m	

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

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Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.h Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 612	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Monocytes_PX612	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> 1.0	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> <i>Low</i> 0.0  <i>High</i> 1.0  <i>Unit</i> 10^6/cu mm	Initial Entry

5.i

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> <b>Sponsor-Defined I</b> 610 <b>dentifier:</b> <b>Test::</b> Basophils_P X610	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

			<b>Result::</b> 0.0	
			<b>Not Done::</b>	
			<b>Lab Normal Range</b> <i>Low</i>	
			:	0.0
				<i>High</i>
				0.5
			<i>Unit</i>	
				10 <sup>6</sup> /cu m
				m

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

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Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.i Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 610	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Basophils_PX610	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> 0.0	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> <i>Low</i> 0.0  <i>High</i> 0.5  <i>Unit</i> 10^6/cu mm	Initial Entry

5.j

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> <b>Sponsor-Defined Identifier:</b> 611 <b>Test::</b> Lymphocytes_PX611	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

			<b>Result::</b> 0.8	
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b> <i>Low</i>	
			0.9	
			<i>High</i>	
			4.4	
			<i>Unit</i>	
			10 <sup>6</sup> /cu mm	

Header Text: C4591001

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Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.j Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 611	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> Lymphocytes_PX611	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u> 0.8	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Nov-09-2020 19:29:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<u>Data Entry:</u>  <i>Low</i> 0.9  <i>High</i> 4.4  <i>Unit</i> 10^6/cu mm	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail  
on Nov/03/2020

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

**Form Status:**

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Date	Location	User	Value	Reason
Nov-09-2020 19:30:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Form Created	



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Nov/03/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Date:**

Date	Location	User	Value	Reason
Nov-09-2020 19:30:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Nov/3/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Nov-09-2020 19:34:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Systolic::</b> 15 3 <b>Diastolic::</b> 97 <b>Respiratory Rate in respirat ions/minute:</b> 32 <b>Heart Rate in beats/minute:</b> 72	Changed Information
Nov-09-2020 19:30:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Systolic::</b> 15 3 <b>Diastolic::</b> 97 <b>Respiratory Rate in respirat ions/minute:</b> 19 <b>Heart Rate in beats/minute:</b> 72	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Nov-09-2020 19:30:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Systolic:**

Date	Location	User	Value	Reason
Nov-11-2020 21:46:42	ACV0PFEINFP6000	(b) (6)	Query 1: Closed	Response satisfies

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History  
on Nov/03/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1221**Site Name:** (1221) Center for American Indian Health - Gallup**Subject No:** 12211002**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11

(UTC-07:00) Mountain Time (US & Canada)		(b)(4),(b)(6)		query
Nov-11-2020 08:20:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	Systolic b/p is not clinically significant
Nov-11-2020 04:53:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Reissued:Opened	DM: Kindly review and confirm the Systolic BP entered is correct and clarify if the event is clinically significant or not.
Nov-09-2020 19:30:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	Original value is correct
Nov-09-2020 19:30:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 153 is outside of Normal Range 90 - 140.
Nov-09-2020 19:30:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> 153	Initial Entry

**2.a Diastolic:**

Date	Location	User	Value	Reason
Nov-12-2020 03:54:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Response satisfies query
Nov-11-2020 08:21:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	B/p is "Not clinically significant"
Nov-10-2020 22:23:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Reissued:Opened	DM: Confirmation on the out of range value as "clinically significant" or "not clinically significant" is expected as a response. Please review and confirm.

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History on Nov/03/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1221**Site Name:** (1221) Center for American Indian Health - Gallup**Subject No:** 12211002**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11

Nov-09-2020 19:31:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Answered	Original value is correct
Nov-09-2020 19:30:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Diastolic BP 97 is outside of Normal Range 60 - 90.
Nov-09-2020 19:30:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> 97	Initial Entry

**2.a Respiratory Rate in respirations/minute:**

Date	Location	User	Value	Reason
Nov-09-2020 19:34:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> 32	Changed Information
Nov-09-2020 19:30:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> 19	Initial Entry

**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Nov-09-2020 19:30:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> 72	Initial Entry

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail on Nov/03/2020

**Form Version:** 10-Oct-2020 16:04

**Form Status:**

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Date	Location	User	Value	Reason
Nov-09-2020 19:31:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Form Created	

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail on Nov/03/2020 History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Date:**

Date	Location	User	Value	Reason
Nov-09-2020 19:31:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Nov/3/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Nov-09-2020 19:31:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Oxygen Saturation:</b> 95.0	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Nov-09-2020 19:31:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> 1	Initial Entry

**2.a SPO2 Pulse Oximetry %**

Date	Location	User	Value	Reason
Nov-09-2020 19:31:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> 95.0	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**1. Date Time of Assessment:**

Date	Location	User	Value	Reason
Nov-11-2020 09:27:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Arterial Blood Gases PaO2 (mmHg):**

Date	Location	User	Value	Reason
Nov-11-2020 09:31:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. FiO2 (Fraction of Inhaled Oxygen):**

Date	Location	User	Value	Reason
Nov-11-2020 09:31:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Nov-11-2020 09:18:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Nov-11-2020 09:18:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Nov-11-2020 09:18:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Not Applicable	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-11-2020 09:18:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Nov-11-2020 09:18:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/03/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

**6. Ongoing?**

Date	Location	User	Value	Reason
Nov-11-2020 09:18:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** IMAGING - Audit Trail  
on Nov/03/2020

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

**Form Status:**

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Date	Location	User	Value	Reason
Nov-09-2020 19:38:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Form Created	

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** IMAGING - Audit Trail  
on Nov/03/2020

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

**Form Status:**

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Date	Location	User	Value	Reason
Nov-11-2020 08:43:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Form Created	

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** IMAGING - eCRF Audit Trail History  
on Nov/03/2020

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Nov-09-2020 19:38:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Nov/3/2020	Initial Entry

**2. Location of Assessment:**

Date	Location	User	Value	Reason
Nov-09-2020 19:38:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> CHEST	Initial Entry

**3. Type of Imaging Exam:**

Date	Location	User	Value	Reason
Nov-09-2020 19:38:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> X-RAY	Initial Entry

**4. Assessment:**

Date	Location	User	Value	Reason
Nov-09-2020 19:38:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> NORMAL	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: IMAGING - eCRF Audit Trail History on Nov/03/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Nov-11-2020 08:43:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Nov/3/2020	Initial Entry

**2. Location of Assessment:**

Date	Location	User	Value	Reason
Nov-11-2020 08:43:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> CHEST	Initial Entry

**3. Type of Imaging Exam:**

Date	Location	User	Value	Reason
Nov-11-2020 08:43:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> CT SCAN	Initial Entry

**4. Assessment:**

Date	Location	User	Value	Reason
Nov-11-2020 08:43:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> ABNORMAL <i>If abnormal, specify findings:</i>  Small patchy density in R Upper lobe, likely inflammatory/infectious with minor bibasilar subsegmental atelectasis; R coronary atherosclerosis vs. stent	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Feb/28/2021**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1221**Site Name:** (1221) Center for American Indian Health - Gallup**Subject No:** 12211002**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Date of Visit**

Date	Location	User	Value	Reason
Mar-01-2021 16:25:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-01-2021 16:22:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Mar-01-2021 16:13:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Mar-01-2021 16:13:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Mar-01-2021 16:13:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Feb/28/2021	Initial Entry

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

Date	Location	User	Value	Reason
Mar-01-2021 16:13:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_B	Initial Entry

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:17

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Mar-01-2021 16:22:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Feb/28/2021	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Mar-01-2021 16:22:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Feb/26/2021	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Mar-05-2021 11:51:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> NO Date of Last Symptom Resolved :  Mar/2/2021	New Information
Mar-01-2021 16:22:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> YES	Initial Entry

**4.a**

Date	Location	User	Value	Reason
Mar-01-2021 16:22:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b> NO	Initial Entry

**4.a Symptoms:**

Date	Location	User	Value	Reason
Mar-01-2021 16:22:42	ACV0PFEINFP6000	(b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 20-Feb-2021 02:17**Form Status:** Data Complete, Frozen, Verified**Site No:** 1221**Site Name:** (1221) Center for American Indian Health - Gallup**Subject No:** 12211002**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11

(UTC-07:00) Mountain Time (US & Canada)		(b)(4), (b)(6)	FEVER	
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**4.a Was symptom present?**

Date	Location	User	Value	Reason
Mar-01-2021 16:22:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> NO	Initial Entry

**4.b**

Date	Location	User	Value	Reason
Mar-01-2021 16:22:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED COUGH <b>Symptom P present:</b> YES	Initial Entry

**4.b Symptoms:**

Date	Location	User	Value	Reason
Mar-01-2021 16:22:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> NEW OR INCREASED COUGH	Initial Entry

**4.b Was symptom present?**

Date	Location	User	Value	Reason
Mar-01-2021 16:22:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> YES	Initial Entry

**4.c**

Date	Location	User	Value	Reason
Mar-01-2021 16:22:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:17

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

			Symptom Present:	NO
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4.c Symptoms:

Date	Location	User	Value	Reason
Mar-01-2021 16:22:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Mar-01-2021 16:22:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Mar-01-2021 16:22:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Symptoms: CHILLS Symptom Present: YES	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Mar-01-2021 16:22:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Mar-01-2021 16:22:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> YES	Initial Entry

4.e

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)



Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:17

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Date	Location	User	Value	Reason
Mar-01-2021 16:22:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Symptom NEW OR INCREASED MUSCLE PAIN Symptom NO Present:	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Mar-01-2021 16:22:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Mar-01-2021 16:22:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Mar-01-2021 16:22:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Symptoms NEW LOSS OF TASTE OR SMELL Symptom YES Present:	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 20-Feb-2021 02:17**Form Status:** Data Complete, Frozen, Verified**Site No:** 1221**Site Name:** (1221) Center for American Indian Health - Gallup**Subject No:** 12211002**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11**4.f Symptoms:**

Date	Location	User	Value	Reason
Mar-01-2021 16:22:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> NEW LOSS OF TASTE OR SME LL	Initial Entry

**4.f Was symptom present?**

Date	Location	User	Value	Reason
Mar-01-2021 16:22:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> YES	Initial Entry

**4.g**

Date	Location	User	Value	Reason
Mar-01-2021 16:22:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Symptom</b> NEW OR INCREAS s: ED SORE THROAT <b>Symptom</b> NO <b>Present:</b>	Initial Entry

**4.g Symptoms:**

Date	Location	User	Value	Reason
Mar-01-2021 16:22:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> NEW OR INCREASED SORE T HROAT	Initial Entry

**4.g Was symptom present?**

Date	Location	User	Value	Reason
Mar-01-2021 16:22:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> NO	Initial Entry

**4.h**

Date	Location	User	Value	Reason
Mar-01-2021 16:22:42	ACV0PFEINFP6000	(b) (6)	<b>Data Entry:</b>	Initial Entry

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:17

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

(UTC-07:00) Mountain Time (US & Canada)		(b)(4), (b)(6)	Symptoms: DIARRHEA Symptom Present: NO	
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4.h Symptoms:

Date	Location	User	Value	Reason
Mar-01-2021 16:22:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Mar-01-2021 16:22:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Mar-01-2021 16:22:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: VOMITING Symptoms: VOMITING Symptom Present: NO	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Mar-01-2021 16:22:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Mar-01-2021 16:22:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
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090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

**Form Version:** 20-Feb-2021 02:17

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

Mar-01-2021 16:23:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Symptoms - Other:</b> nasal congestion	Initial Entry
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**5.a Symptoms - Other Text:**

Date	Location	User	Value	Reason
Mar-01-2021 16:23:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> nasal congestion	Initial Entry

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail  
on Feb/28/2021

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

**Form Status:**

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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Date	Location	User	Value	Reason
Mar-05-2021 15:55:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Form Created	

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Feb/28/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Mar-05-2021 15:55:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> Mar/4/2021	Initial Entry
Mar-05-2021 15:42:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b>	Initial Entry
Mar-01-2021 16:24:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Mar-05-2021 15:55:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> SWABBED MATERIAL	Initial Entry
Mar-05-2021 15:42:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b>	Initial Entry
Mar-01-2021 16:24:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Mar-05-2021 15:55:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> NASOPHARYNX	Initial Entry
Mar-05-2021 15:42:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b>	Initial Entry
Mar-01-2021 16:24:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Feb/28/2021

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Mar-05-2021 15:55:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RESP SYNDR OME CORONAVIRUS 2	Initial Entry
Mar-05-2021 15:42:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b>	Initial Entry
Mar-01-2021 16:24:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Mar-05-2021 15:55:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGNOSTIC TE ST	Initial Entry
Mar-05-2021 15:42:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b>	Initial Entry
Mar-01-2021 16:24:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Mar-05-2021 15:56:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-05-2021 15:55:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Trade Name is not Other, however Trade Name Other, Specify is completed. Please verify and correct inconsistency.

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Feb/28/2021

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

Mar-05-2021 15:55:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> CEPHEID XPERT XPRESS SA RS-COV-2 TEST	Initial Entry
Mar-05-2021 15:42:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b>	Initial Entry
Mar-01-2021 16:24:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**7. Test Result:**

Date	Location	User	Value	Reason
Mar-05-2021 15:55:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> POSITIVE	Initial Entry
Mar-05-2021 15:42:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b>	Initial Entry
Mar-01-2021 16:24:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**8. Comments/Findings/Details:**

Date	Location	User	Value	Reason
Mar-05-2021 15:55:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> Cepheid IQC4PLEX	Initial Entry
Mar-05-2021 15:42:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b>	Initial Entry
Mar-01-2021 16:24:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**9. Trade Name Other, Specify:**

Date	Location	User	Value	Reason
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090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Feb/28/2021

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

Mar-05-2021 15:56:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b>	Changed Information
Mar-05-2021 15:55:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> Cepheid	Initial Entry
Mar-05-2021 15:42:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b>	Initial Entry
Mar-01-2021 16:24:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1221**Subject No:** 12211002**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1221) Center for American Indian Health - Gallup**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Mar-01-2021 16:25:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-01-2021 16:25:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-01-2021 16:27:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-01-2021 16:25:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-01-2021 16:25:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> YES Date of Collection: Feb/27/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-01-2021 16:27:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Sample ID: CV55142	Initial Entry

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

**5.a Sample ID**

Date	Location	User	Value	Reason
Mar-01-2021 16:27:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> CV55142	Initial Entry

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**1. Data Origin**

Date	Location	User	Value	Reason
Mar-01-2021 16:27:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-01-2021 16:27:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-01-2021 16:27:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> NO	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Mar-01-2021 16:27:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Self swab collected	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Feb/28/2021

Form Version: 20-Feb-2021 02:19

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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*1.a*

Date	Location	User	Value	Reason
Mar-01-2021 16:28:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIA LIST <b>Occurrence of Visits o r Contacts:</b>	Initial Entry

*1.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Mar-01-2021 16:28:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> SPECIALIST	Initial Entry

*1.a Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Mar-01-2021 16:28:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> NO	Initial Entry

*1.b*

Date	Location	User	Value	Reason
Mar-01-2021 16:28:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Type of Practition</b> EMERGEN <b>er:</b> CY ROOM <b>Occurrence of Vis NO its or Contacts:</b>	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Feb/28/2021**Form Version:** 20-Feb-2021 02:19**Form Status:** Data Complete, Frozen, Verified**Site No:** 1221**Site Name:** (1221) Center for American Indian Health - Gallup**Subject No:** 12211002**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11***I.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Mar-01-2021 16:28:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

***I.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Mar-01-2021 16:28:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> NO	Initial Entry

***I.c***

Date	Location	User	Value	Reason
Mar-01-2021 16:28:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

***I.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Mar-01-2021 16:28:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

***I.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Mar-01-2021 16:28:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> NO	Initial Entry

***I.d***

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Feb/28/2021

Form Version: 20-Feb-2021 02:19

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

Mar-01-2021 16:28:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Type of Practitioner</b> URGENT : CARE <b>Occurrence of Visits</b> NO <b>or Contacts:</b>	Initial Entry
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*1.d Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Mar-01-2021 16:28:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> URGENT CARE	Initial Entry

*1.d Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Mar-01-2021 16:28:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> NO	Initial Entry

*1.e*

Date	Location	User	Value	Reason
Mar-01-2021 16:28:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Type of Practiti</b> TELEPHONE <b>oner:</b> CONSULTATI ON <b>Occurrence of</b> NO <b>Visits or Conta</b> <b>cts:</b>	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Feb/28/2021**Form Version:** 20-Feb-2021 02:19**Form Status:** Data Complete, Frozen, Verified**Site No:** 1221**Site Name:** (1221) Center for American Indian Health - Gallup**Subject No:** 12211002**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Mar-01-2021 16:28:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> TELEPHONE CONSULTATION	Initial Entry

***1.e Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Mar-01-2021 16:28:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> NO	Initial Entry

***1.f***

Date	Location	User	Value	Reason
Mar-01-2021 16:28:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTH ER <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

***1.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Mar-01-2021 16:28:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> OTHER	Initial Entry

***1.f Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Mar-01-2021 16:28:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> NO	Initial Entry

***3. Has the subject been hospitalized due to potential COVID-19 illness?***

Date	Location	User	Value	Reason
Mar-01-2021 16:28:07	ACV0PFEINFP6000	(b) (6)	<b>Data Entry:</b>	Initial Entry



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Feb/28/2021

**Form Version:** 20-Feb-2021 02:19

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

(UTC-07:00) Mountain  
Time (US & Canada)

(b)(4),  
(b)(6)

NO

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - eCRF Audit Trail History on Feb/28/2021

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**1. Hospitalization Category:**

Date	Location	User	Value	Reason
Mar-01-2021 16:28:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Hospitalization Term:**

Date	Location	User	Value	Reason
Mar-01-2021 16:28:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Admission Date:**

Date	Location	User	Value	Reason
Mar-01-2021 16:28:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Ongoing?**

Date	Location	User	Value	Reason
Mar-01-2021 16:28:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit Form: RESPIRATORY TREATMENT - eCRF Audit Trail History on Feb/28/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

[Back to Form](#)

**1. What is the treatment Identifier?**

Date	Location	User	Value	Reason
Mar-01-2021 16:29:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Concomitant Non-drug Treatment Pre-specified:**

Date	Location	User	Value	Reason
Mar-01-2021 16:29:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Treatment:**

Date	Location	User	Value	Reason
Mar-01-2021 16:29:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Treatment:**

Date	Location	User	Value	Reason
Mar-01-2021 16:29:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Mar-01-2021 16:29:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Ongoing?**

Date	Location	User	Value	Reason
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090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History on Feb/28/2021

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

Mar-01-2021 16:29:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History  
on Feb/28/2021**Form Version:** 06-Jul-2020 21:52**Form Status:** Data Complete, Verified**Site No:** 1221**Site Name:** (1221) Center for American Indian Health - Gallup**Subject No:** 12211002**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Mar-09-2021 16:42:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Closed	Response satisfies query
Mar-09-2021 12:22:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Answered	COVID illness is uploaded under folder "COVID Illness", subfolder, "CI-B".
Mar-08-2021 18:33:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Opened	Blinded monitor is unable to verify source documentation. Please ensure source is uploaded into Florence within 24 hours due to BLA submission. Data cut to take place on 19th March 2021.
Mar-01-2021 16:30:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID-19 ILL NESS	Initial Entry

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

Date	Location	User	Value	Reason
Mar-09-2021 06:21:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Closed	Response satisfies query
Mar-08-2021 17:06:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Mar-08-2021 17:06:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnosis:</i>	Changed Information

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History  
on Feb/28/2021

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

**Form Status:** Data Complete, Verified

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

			COVID-19 Date of Diagnosis: Mar/4/2021	
Mar-08-2021 11:14:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Opened	CLIQUEY: Subject has confirmed COVID-19 (symptoms and positive test), please update diagnosis to COVID-19.
Mar-01-2021 16:30:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> NO	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Mar-01-2021 16:35:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-01-2021 16:35:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> 1	Transcription Error
Mar-01-2021 16:30:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Please enter worst toxicity grade (1 to 5) as it relates to reported symptom(s) on Signs and Symptoms CRF. Please review and update as appropriate.
Mar-01-2021 16:30:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> 0	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Feb/28/2021

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Mar-01-2021 16:30:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Subcategory of Clinical Event:**

Date	Location	User	Value	Reason
Mar-01-2021 16:30:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Was a diagnosis obtained?**

Date	Location	User	Value	Reason
Mar-01-2021 16:30:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Toxicity Grade:**

Date	Location	User	Value	Reason
Mar-01-2021 16:30:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Mar-01-2021 16:31:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Mar-01-2021 16:31:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Mar-01-2021 16:31:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Mar-01-2021 16:31:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-01-2021 16:31:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Sponsor-Defined Id</b> Not Applicable <b>entifier:</b> <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

			<b>Not Done::</b> Not Applicable	
			<b>Lab Normal Range:</b> Not Applicable	

**5.a Sponsor ID:**

Date	Location	User	Value	Reason
Mar-01-2021 16:31:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a Test:**

Date	Location	User	Value	Reason
Mar-01-2021 16:31:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a Result:**

Date	Location	User	Value	Reason
Mar-01-2021 16:31:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a Not Done:**

Date	Location	User	Value	Reason
Mar-01-2021 16:31:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a LNMT**

Date	Location	User	Value	Reason
Mar-01-2021 16:31:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b**

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

Date	Location	User	Value	Reason
Mar-01-2021 16:31:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.b Sponsor ID:

Date	Location	User	Value	Reason
Mar-01-2021 16:31:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Mar-01-2021 16:31:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Mar-01-2021 16:31:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Mar-01-2021 16:31:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Mar-01-2021 16:31:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-01-2021 16:31:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Sponsor-Defined Id</b> Not Applicable <b>entifier:</b> able	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

			<b>Test::</b>	Not Applicable	
			<b>Result::</b>	Not Applicable	
			<b>Not Done::</b>	Not Applicable	
			<b>Lab Normal Range:</b>	Not Applicable	

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.c Sponsor ID:

Date	Location	User	Value	Reason
Mar-01-2021 16:31:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Mar-01-2021 16:31:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Mar-01-2021 16:31:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Mar-01-2021 16:31:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Mar-01-2021 16:31:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Mar-01-2021 16:31:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Sponsor-Defined Id</b> Not Applicable <b>entifier:</b> able	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

			<b>Test::</b>	Not Applicable	
			<b>Result::</b>	Not Applicable	
			<b>Not Done::</b>	Not Applicable	
			<b>Lab Normal Range:</b>	Not Applicable	

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.d Sponsor ID:

Date	Location	User	Value	Reason
Mar-01-2021 16:31:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Mar-01-2021 16:31:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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5.d LNMT

Date	Location	User	Value	Reason
Mar-01-2021 16:31:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
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090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

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**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

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**Generated Time (GMT):** 29-Mar-2021 13:11

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5.e Not Done:

Date	Location	User	Value	Reason
Mar-01-2021 16:31:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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**Generated Time (GMT):** 29-Mar-2021 13:11

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			<b>Lab Normal Range:</b>	Not Applicable	

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5.g

Date	Location	User	Value	Reason
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090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

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			<b>Result::</b>	Not Applicable	
			<b>Not Done::</b>	Not Applicable	
			<b>Lab Normal Range:</b>	Not Applicable	

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**5.g Sponsor ID:**

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**5.g Test:**

Date	Location	User	Value	Reason
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**5.g Result:**

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Date	Location	User	Value	Reason
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**5.g LNMT**

Date	Location	User	Value	Reason
Mar-01-2021 16:31:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Sponsor-Defined Id</b> Not Applicable <b>entifier:</b> <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

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**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

			<b>Not Done::</b> Not Applicable	
			<b>Lab Normal Range:</b> Not Applicable	

**5.a Sponsor ID:**

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a Test:**

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a Result:**

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a Not Done:**

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a LNMT**

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b**

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Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry



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5.b Sponsor ID:

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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Sponsor-Defined Id</b> Not Applicable <b>entifier:</b> able	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

			<b>Test::</b>	Not Applicable	
			<b>Result::</b>	Not Applicable	
			<b>Not Done::</b>	Not Applicable	
			<b>Lab Normal Range:</b>	Not Applicable	



Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.f Sponsor ID:

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Sponsor-Defined Id</b> Not Applicable <b>entifier:</b> able	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

			<b>Test::</b>	Not Applicable	
			<b>Result::</b>	Not Applicable	
			<b>Not Done::</b>	Not Applicable	
			<b>Lab Normal Range:</b>	Not Applicable	

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.g Sponsor ID:

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.h

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Sponsor-Defined Id</b> Not Applicable <b>entifier:</b> able	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

			<b>Test::</b>	Not Applicable	
			<b>Result::</b>	Not Applicable	
			<b>Not Done::</b>	Not Applicable	
			<b>Lab Normal Range:</b>	Not Applicable	

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.h Sponsor ID:

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.i

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Sponsor-Defined Id</b> Not Applicable <b>entifier:</b> able	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

			<b>Test::</b>	Not Applicable	
			<b>Result::</b>	Not Applicable	
			<b>Not Done::</b>	Not Applicable	
			<b>Lab Normal Range:</b>	Not Applicable	

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**5.i Sponsor ID:**

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i Test:**

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i Result:**

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i Not Done:**

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i LNMT**

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.j**

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (6)	<b>Data Entry:</b> Sponsor-Defined Id Not Applic	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

Time (US & Canada)	(b) (4)	<b>entifier:</b>	able
		<b>Test::</b>	Not Applicable
		<b>Result::</b>	Not Applicable
		<b>Not Done::</b>	Not Applicable
		<b>Lab Normal Range:</b>	Not Applicable



Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.j Sponsor ID:

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Mar-01-2021 16:31:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History on Feb/28/2021**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1221**Site Name:** (1221) Center for American Indian Health - Gallup**Subject No:** 12211002**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Mar-01-2021 16:32:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Mar-01-2021 16:32:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Record Identifier::</b> Not Applicable <b>Systolic::</b> Not Applicable <b>Diastolic::</b> Not Applicable <b>Respiratory Rate in re</b> Not App <b>spirations/minute:</b> licable <b>Heart Rate in beats/mi</b> Not App <b>nute:</b> licable	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Mar-01-2021 16:32:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a Systolic:**

Date	Location	User	Value	Reason
Mar-01-2021 16:32:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a Diastolic:**

Date	Location	User	Value	Reason
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History on Feb/28/2021

**Form Version:** 10-Oct-2020 15:59

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

Mar-01-2021 16:32:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**2.a Respiratory Rate in respirations/minute:**

Date	Location	User	Value	Reason
Mar-01-2021 16:32:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Mar-01-2021 16:32:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Date:**

Date	Location	User	Value	Reason
Mar-01-2021 16:33:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Mar-01-2021 16:33:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Record Identifier</b> Not Applicab :: le <b>Oxygen Saturatio</b> Not Applicab <b>n:</b> le	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Mar-01-2021 16:33:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a SPO2 Pulse Oximetry %**

Date	Location	User	Value	Reason
Mar-01-2021 16:33:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History on Feb/28/2021

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

[Back to Form](#)

**1. Date Time of Assessment:**

Date	Location	User	Value	Reason
Mar-01-2021 16:33:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Arterial Blood Gases PaO2 (mmHg):**

Date	Location	User	Value	Reason
Mar-01-2021 16:33:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. FiO2 (Fraction of Inhaled Oxygen):**

Date	Location	User	Value	Reason
Mar-01-2021 16:33:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Mar-01-2021 16:33:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Mar-01-2021 16:33:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Mar-01-2021 16:33:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	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
Mar-01-2021 16:33:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Mar-01-2021 16:33:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Feb/28/2021

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

**6. Ongoing?**

Date	Location	User	Value	Reason
Mar-01-2021 16:33:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** IMAGING - eCRF Audit Trail History  
on Feb/28/2021

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Mar-01-2021 16:34:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Location of Assessment:**

Date	Location	User	Value	Reason
Mar-01-2021 16:34:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Type of Imaging Exam:**

Date	Location	User	Value	Reason
Mar-01-2021 16:34:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Assessment:**

Date	Location	User	Value	Reason
Mar-01-2021 16:34:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled Visit on Dec/04/2020

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

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**1. Date of Visit**

Date	Location	User	Value	Reason
Dec-04-2020 12:05:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Dec/4/2020	Initial Entry

**3. COVID-19 Illness Visit:**

Date	Location	User	Value	Reason
Dec-04-2020 12:05:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> COVID_A1	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Dec/04/2020**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1221**Site Name:** (1221) Center for American Indian Health - Gallup**Subject No:** 12211002**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-04-2020 12:07:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-04-2020 12:07:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-04-2020 12:07:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-04-2020 12:07:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-04-2020 12:07:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> YES Date of Collection:  Dec/4/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-04-2020 12:07:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Sample ID:</b> BR8BX8	Initial Entry

Header Text: C4591001

Visit: POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Dec/04/2020

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.a Sample ID

Date	Location	User	Value	Reason
Dec-04-2020 12:07:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> BR8BX8	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-04-2020 12:20:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Sample ID: BS723W</b>	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-04-2020 12:20:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> BS723W	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-04-2020 12:20:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> <b>Sample ID: BS723X</b>	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-04-2020 12:20:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> BS723X	Initial Entry

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**Header Text:** C4591001

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**Form Version:** 22-Apr-2020 21:02

**Site No:** 1221

**Subject No:** 12211002

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

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Date	Location	User	Value	Reason
Nov-09-2020 18:24:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Form Deleted	Transcription Error
Nov-03-2020 14:34:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	Form Created	

Header Text: C4591001

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Site No: 1221

Subject No: 12211002

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Nov-03-2020 14:34:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-03-2020 14:34:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-11-2020 00:44:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Closed	Response satisfies query
Nov-09-2020 18:24:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Nov-08-2020 14:24:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Opened	Clin: Per protocol section 8.3.7., potential COVID-19 event does not qualify as AE and please should be documented ONLY on the ILLNESS DETAILS CRF form and should not be captured on the AE CRF page.
Nov-05-2020 04:26:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6) [redacted] [redacted]	Query 1: Closed	event downgraded in Safety database, new query issued

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Site No: 1221

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Generated By: (b) (4)

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Form Status: Data Complete, Deleted, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

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Nov-04-2020 21:51:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Opened	SAE RECON: AER#2020427759,the term was reported as 'Rapid COVID test was positive' in Safety database while recorded as 'COVID-19' in AE CRF. Please confirm correct term. If safety update is required, please submit a follow-up form.
Nov-03-2020 14:34:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<u>Data Entry:</u> COVID-19	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-03-2020 14:34:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<u>Data Entry:</u> Nov/1/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-03-2020 14:34:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<u>Data Entry:</u> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-03-2020 14:34:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<u>Data Entry:</u> 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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Generated By: (b) (4)

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Form Status: Data Complete, Deleted, Verified

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*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-09-2020 18:24:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Deleted	Transcription Error
Nov-05-2020 20:24:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Reissued:Candi date	SAE RECON:Pending SDB update
Nov-05-2020 09:18:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	Query 2: Answered	Subject was hospitalized due to this illness, so should be an SAE. SAE paperwork has been faxed in.
Nov-05-2020 04:30:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 2: Opened	SAE RECON:AER#2020427759, Rapid COVID test was positive was downgraded in Safety database.However, reported as serious in Inform. Please confirm if event was reported correctly as an SAE and update accordingly.
Nov-04-2020 05:09:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-03-2020 14:34:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE COVID-19: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.

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Generated By: (b) (4)

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Form Status: Data Complete, Deleted, Verified

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<p>Nov-03-2020 14:34:37 (UTC-07:00) Mountain Time (US &amp; Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>Dan VandeRiet (b) (4)</p>	<p><b>Data Entry:</b> 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  NO</p>	<p>Initial Entry</p>
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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
<p>Nov-03-2020 14:34:37 (UTC-07:00) Mountain Time (US &amp; Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>Dan VandeRiet (b) (4)</p>	<p><b>Data Entry:</b> NO</p>	<p>Initial Entry</p>

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Header Text: C4591001

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Subject No: 12211002

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-03-2020 14:34:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandRiet (b) (4)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  If Other, specify:  Viral infection	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-03-2020 14:34:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandRiet (b) (4)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-04-2020 17:29:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandRiet (b) (4)	<b>Data Entry:</b> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-04-2020 17:29:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandRiet (b) (4)	<b>Data Entry:</b> YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Nov-03-2020 14:34:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandRiet (b) (4)	<b>Data Entry:</b> NOT RECOVERED/NOT RESOLVED	Initial Entry

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**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Deleted, Verified

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**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Nov-03-2020 14:34:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dan VandeRiet (b) (4)	<b>Data Entry:</b> NO	Initial Entry

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Nov-04-2020 05:09:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> 2020427759	Initial Entry

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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Date	Location	User	Value	Reason
Oct-19-2020 16:55:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Form Deleted	Transcription Error
Oct-15-2020 13:40:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Form Created	

**Header Text:** C4591001

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Date	Location	User	Value	Reason
Oct-19-2020 16:56:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Form Deleted	Transcription Error
Oct-15-2020 13:47:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Form Created	

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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VACCINATIONS - Audit Trail

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**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

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Date	Location	User	Value	Reason
Oct-19-2020 16:57:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Form Deleted	Transcription Error
Oct-15-2020 13:48:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Form Created	

**Header Text:** C4591001

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Date	Location	User	Value	Reason
Oct-19-2020 16:57:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Form Deleted	Transcription Error
Oct-15-2020 13:49:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Form Created	

**Header Text:** C4591001

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Date	Location	User	Value	Reason
Oct-19-2020 16:58:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Form Deleted	Transcription Error
Oct-15-2020 13:50:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Form Created	

**Header Text:** C4591001

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Oct-19-2020 16:58:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Form Deleted	Transcription Error
Oct-15-2020 13:51:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Form Created	



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Date	Location	User	Value	Reason
Oct-19-2020 16:59:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Form Deleted	Transcription Error
Oct-15-2020 13:52:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Form Created	

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Date	Location	User	Value	Reason
Oct-19-2020 16:59:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Form Deleted	Transcription Error
Oct-15-2020 13:53:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Form Created	

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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Date	Location	User	Value	Reason
Oct-19-2020 16:59:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Form Deleted	Transcription Error
Oct-15-2020 13:54:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Form Created	

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Oct-19-2020 17:00:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Form Deleted	Transcription Error
Oct-15-2020 13:56:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Form Created	

**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:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

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Date	Location	User	Value	Reason
Oct-19-2020 17:00:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Form Deleted	Transcription Error
Oct-15-2020 13:58:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Form Created	

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
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**Form Version:** 22-Apr-2020 21:03

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**Site Name:** (1221) Center for American Indian Health - Gallup

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**Generated Time (GMT):** 29-Mar-2021 13:11

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Date	Location	User	Value	Reason
Oct-19-2020 17:00:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Form Deleted	Transcription Error
Oct-15-2020 14:00:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY  
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Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

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Generated By: (b) (4)

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Oct-18-2020 15:43:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 13:40:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 1	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Oct-18-2020 15:43:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 13:40:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> VACCINATIONS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Oct-18-2020 15:43:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 13:40:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 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
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090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**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:** Incomplete, Data Complete, Deleted, Verified

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

Oct-18-2020 15:43:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b>	Transcription Error
Oct-15-2020 13:42:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Metformin, 1000 mg/day Tablet PO for diabetes	New Information
Oct-15-2020 13:40:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Metformin	Initial Entry

**5. Date:**

Date	Location	User	Value	Reason
Oct-18-2020 15:45:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b>	Transcription Error
Oct-15-2020 13:40:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> UNK/UNK/2020	Initial Entry

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Site Name: (1221) Center for American Indian Health - Gallup

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Oct-18-2020 15:44:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 13:47:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 2	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Oct-18-2020 15:44:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 13:47:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> VACCINATIONS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Oct-18-2020 15:44:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 13:47:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 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
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090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

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**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

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Oct-18-2020 16:20:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Oct-18-2020 15:44:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-18-2020 15:44:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b>	Transcription Error
Oct-16-2020 01:38:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify NOVOLOG (INSULIN ASPARTATE) 25U SQ TID FOR T2D as follows...Should the spelling be NOVOLOG (INSULIN ASPART) 25U SQ TID FOR T2D? If so, update the verbatim term as such. Otherwise clarify and update the term as appropriate or provide reference/label. Thank you.
Oct-15-2020 13:47:40 (UTC-07:00) Mountain Time	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Novolog (Insulin Aspartate) 25u SQ TID	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
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**Form Version:** 22-Apr-2020 21:03

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**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

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(US & Canada)

for T2D

**5. Date:**

Date	Location	User	Value	Reason
Oct-18-2020 15:44:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b>	Changed Information
Oct-15-2020 13:47:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> UNK/UNK/2020	Initial Entry

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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**Site No:** 1221

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**Generated By:** (b) (4)

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\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Oct-18-2020 15:47:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 13:48:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 3	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Oct-18-2020 15:47:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 13:48:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> VACCINATIONS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Oct-18-2020 15:47:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 13:48:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 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
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090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
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**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

Oct-18-2020 15:47:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b>	Transcription Error
Oct-15-2020 13:48:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Basaglar (Insulin glargine) 35u S Q Qpm for T2D	Initial Entry

**5. Date:**

Date	Location	User	Value	Reason
Oct-18-2020 15:46:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b>	Transcription Error
Oct-15-2020 13:48:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> UNK/UNK/2020	Initial Entry

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\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Oct-18-2020 15:47:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 13:49:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 4	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Oct-18-2020 15:47:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 13:49:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> VACCINATIONS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Oct-18-2020 15:47:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 13:49:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 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
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090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

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**Generated Time (GMT):** 29-Mar-2021 13:11

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Oct-18-2020 15:47:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b>	Transcription Error
Oct-15-2020 13:49:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Atorvastatin 60 md tablet PO Q D for high cholesterol	Initial Entry

**5. Date:**

Date	Location	User	Value	Reason
Oct-18-2020 15:48:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b>	Transcription Error
Oct-15-2020 13:49:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> UNK/UNK/2020	Initial Entry

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Header Text: C4591001

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\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Oct-18-2020 15:48:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 13:50:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 5	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Oct-18-2020 15:48:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 13:50:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> VACCINATIONS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Oct-18-2020 15:48:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 13:50:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 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
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090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)



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Oct-18-2020 15:48:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b>	Transcription Error
Oct-15-2020 14:01:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Flomax (Tamsulosin) 50 mg tab PO QD for BPH	Transcription Error
Oct-15-2020 13:50:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Flomax (Tamsulosin 50 mg tab PO QD for BPH	Initial Entry

**5. Date:**

Date	Location	User	Value	Reason
Oct-18-2020 15:48:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b>	Transcription Error
Oct-15-2020 13:50:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> UNK/UNK/2020	Initial Entry

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Oct-18-2020 15:48:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 13:51:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 6	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Oct-18-2020 15:48:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 13:51:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> VACCINATIONS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Oct-18-2020 15:48:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 13:51:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 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
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090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

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Oct-18-2020 15:48:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b>	Transcription Error
Oct-15-2020 14:03:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Metoprolol 125 mg tab PO QD f or HTN	Transcription Error
Oct-15-2020 13:57:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Metapropolol 125 mg tab PO Q D for HTN	Transcription Error
Oct-15-2020 13:51:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Tamsulosin 60 mg tab po QD for BPH	Initial Entry

**5. Date:**

Date	Location	User	Value	Reason
Oct-18-2020 15:48:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b>	Transcription Error
Oct-15-2020 13:51:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> UNK/UNK/2020	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

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: Incomplete, Data Complete, Deleted, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Oct-18-2020 15:49:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 13:52:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 7	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Oct-18-2020 15:49:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 13:52:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> VACCINATIONS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Oct-18-2020 15:49:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 13:52:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 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
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090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**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:** Incomplete, Data Complete, Deleted, Verified

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

Oct-18-2020 15:49:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	<b>Data Entry:</b>	Transcription Error
Oct-15-2020 13:52:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Furosemide 20 mg tab PO QD fo r CHF	Initial Entry

**5. Date:**

Date	Location	User	Value	Reason
Oct-18-2020 15:49:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b) (6)	<b>Data Entry:</b>	Transcription Error
Oct-15-2020 13:52:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> UNK/UNK/2020	Initial Entry

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Site No: 1221

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Oct-18-2020 15:49:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 13:53:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 8	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Oct-18-2020 15:49:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 13:53:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> VACCINATIONS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Oct-18-2020 15:49:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 13:53:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 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
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090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

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VACCINATIONS - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Incomplete, Data Complete, Deleted, Verified

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

Oct-18-2020 15:49:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b>	Transcription Error
Oct-15-2020 13:53:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Potassium Cl tab 20 mg PO QD for CHF	Initial Entry

**5. Date:**

Date	Location	User	Value	Reason
Oct-18-2020 15:49:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b>	Transcription Error
Oct-15-2020 13:53:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> UNK/UNK/2020	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

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: Incomplete, Data Complete, Deleted, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Oct-18-2020 15:50:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 13:54:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 9	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Oct-18-2020 15:50:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 13:54:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> VACCINATIONS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Oct-18-2020 15:50:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 13:54:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 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
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090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)



**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:** Incomplete, Data Complete, Deleted, Verified

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

Oct-18-2020 16:19:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Oct-18-2020 15:50:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-18-2020 15:50:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b>	Transcription Error
Oct-16-2020 01:38:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify EZETIMIDE 10 MG TAB PO QD FOR T2DM as follows...Should the spelling be EZETIMIBE 10 MG TAB PO QD FOR T2DM? If so, update the verbatim term as such. Otherwise clarify and update the term as appropriate or provide reference/label. Thank you.
Oct-15-2020 13:54:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Ezetimide 10 mg tab PO QD for T2DM	Initial Entry

5. Date:

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

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**Site No:** 1221

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**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

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Date	Location	User	Value	Reason
Oct-18-2020 15:50:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b>	Transcription Error
Oct-15-2020 13:54:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> UNK/UNK/2020	Initial Entry

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS - eCRF Audit Trail History

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Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Oct-18-2020 15:50:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 13:56:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 10	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Oct-18-2020 15:50:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 13:56:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> VACCINATIONS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Oct-18-2020 15:50:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 13:56:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 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
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090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**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:** Incomplete, Data Complete, Deleted, Verified

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

Oct-18-2020 16:19:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Clo sed	Discrepancy has been closed.
Oct-18-2020 15:50:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swered	Transcription Error
Oct-18-2020 15:50:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b>	Transcription Error
Oct-16-2020 01:38:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Op ened	Clarify ALOGLIPTIN- PIOGLITIZONE 25MG/45MG PO QD FOR T2DM as follows...Should the spelling be ALOGLIPTIN- PIOGLITAZONE 25MG/45MG PO QD FOR T2DM? If so, update the verbatim term as such. Otherwise clarify and update the term as appropriate or provide reference/label. Thank you.
Oct-15-2020 13:56:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Alogliptin-Pi oglitizone 25 mg/45mg P O QD for T2	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

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**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS - eCRF Audit Trail History

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**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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**5. Date:**

Date	Location	User	Value	Reason
Oct-18-2020 15:50:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b>	Transcription Error
Oct-15-2020 13:56:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> UNK/UNK/2020	Initial Entry

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY  
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Site No: 1221

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\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Oct-18-2020 15:50:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 13:58:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 11	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Oct-18-2020 15:50:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 13:58:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> VACCINATIONS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Oct-18-2020 15:50:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 13:58:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 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
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090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**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:** Incomplete, Data Complete, Deleted, Verified

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

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**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

Oct-18-2020 15:50:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b>	Transcription Error
Oct-15-2020 13:58:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Plavix 10 mg tab PO QD for CA D	Initial Entry

**5. Date:**

Date	Location	User	Value	Reason
Oct-18-2020 15:51:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b>	Transcription Error
Oct-15-2020 13:58:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> UNK/UNK/2020	Initial Entry

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Oct-18-2020 15:51:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 14:00:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 12	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Oct-18-2020 15:51:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 14:00:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> VACCINATIONS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Oct-18-2020 15:51:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Oct-15-2020 14:00:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 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
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090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
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**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

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Oct-18-2020 15:51:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b>	Transcription Error
Oct-15-2020 14:00:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Isosorbide 60 mg tab PO QD for CAD	Initial Entry

**5. Date:**

Date	Location	User	Value	Reason
Oct-18-2020 15:51:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b>	Transcription Error
Oct-15-2020 14:00:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> UNK/UNK/2020	Initial Entry

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**Header Text:** C4591001

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**Subject No:** 12211002

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

**Form Status:**

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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Date	Location	User	Value	Reason
Feb-22-2021 10:08:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Form Deleted	Dexamethasone is not an prohibited medication and was entered in error.
Nov-11-2020 10:32:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Form Created	

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1221

**Subject No:** 12211002

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

**Form Status:**

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

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Date	Location	User	Value	Reason
Feb-19-2021 16:35:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6) [REDACTED]	Form Deleted	Dexamethasone is not a prohibited medication. Entered in error
Nov-11-2020 10:36:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Form Created	

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1221

**Subject No:** 12211002

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

**Form Status:**

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

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Date	Location	User	Value	Reason
Nov-16-2020 23:01:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6) [REDACTED]	Form Deleted	Deleted per query
Nov-11-2020 10:41:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Form Created	

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1221

**Subject No:** 12211002

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

**Form Status:**

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Date	Location	User	Value	Reason
Nov-16-2020 23:02:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6) [REDACTED]	Form Deleted	Deleted per query
Nov-11-2020 10:42:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	Form Created	

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Header Text: C4591001

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Form Status: Data Complete, Deleted, Verified

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Generated By: (b) (4)

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Nov-11-2020 10:32:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Nov-11-2020 10:32:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<u>Data Entry:</u> CORTICOSTEROIDS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Nov-11-2020 10:32:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 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
Feb-22-2021 12:30:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Closed	Response satisfies query
Feb-22-2021 10:05:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Answered	Dexamethasone is not a prohibited medication and was entered in error.
Feb-22-2021 01:12:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (6)	Query 1: Opened	CLINQUERY: Dexamethasone is reported as a

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Header Text: C4591001

Visit: Logs - Unscheduled

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Subject Initials: ---

Generated By: (b) (4)

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		(b) (4)		Prohibited Medication. As this corticosteroid was not taken for 14 days, please verify it is not a prohibited medication per section 6.5.1 of the protocol. Therefore, please verify it was entered in error.
Feb-19-2021 13:40:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Candidate	CLINQUERY: Dexamethasone is reported as a Prohibited Medication. As this corticosteroid was not taken for 14 days, please verify it is not a prohibited medication per section 6.5.1 of the protocol. Therefore, please verify it was entered in error.
Nov-11-2020 10:32:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Dexamethasone (Decadron)	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Nov-11-2020 10:32:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> 6	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Nov-11-2020 10:32:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> mg	Initial Entry

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Generated By: (b) (4)

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Time (US & Canada)				
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7. Dose Frequency:

Date	Location	User	Value	Reason
Nov-11-2020 10:32:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> QD	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Nov-11-2020 10:32:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> INTRAVENOUS	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Nov-11-2020 10:33:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-11-2020 10:33:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Nov/3/2020	Transcription Error
Nov-11-2020 10:32:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For Dexamethasone (Decadron) Start Date 03/Nov/2022, is a future date relative to when it was entered on 11/Nov/2020. Please correct.
Nov-11-2020 10:32:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Nov/3/2022	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
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**Generated By:** (b) (4)

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Nov-11-2020 10:34:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> NO End Date:  Nov/6/2020	Changed Information
Nov-11-2020 10:32:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> YES	Initial Entry

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[Back to Form](#)**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Nov-11-2020 10:36:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Nov-11-2020 10:36:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> CORTICOSTEROIDS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Nov-11-2020 10:36:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry

**4. Medication:**

*Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).*

Date	Location	User	Value	Reason
Nov-11-2020 10:36:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Dexamethasone	Initial Entry

**5. Dose:**

Date	Location	User	Value	Reason
Nov-11-2020 10:36:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> 6	Initial Entry

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6. Dose Unit:

Date	Location	User	Value	Reason
Nov-11-2020 10:36:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<u>Data Entry:</u> mg	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Nov-11-2020 10:36:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<u>Data Entry:</u> QD	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Nov-11-2020 10:36:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<u>Data Entry:</u> ORAL	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Nov-11-2020 10:36:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<u>Data Entry:</u> Nov/7/2020	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Feb-22-2021 08:12:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Closed	Response satisfies query
Feb-19-2021 16:35:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Dexamethasone is not a prohibited medication. Entered in error
Feb-19-2021 13:38:24	ACV0PFEINFP6000	(b) (6)	Query 1: Reissued:Opened	CLINQUERY:

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(UTC-07:00) Mountain Time (US & Canada)		(b)(4), (b)(6)		Query response confirms con med was not prohibited and was entered in error. However, it is still reported. Please verify that both the IV and Oral entries of Dexamethasone were entered in error and update CRF accordingly.
Feb-19-2021 12:34:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Answered	This medication is not a prohibited medication per protocol and was entered in error.
Feb-17-2021 07:38:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	Query 1: Reissued:Opened	CLINQUERY: Thank you for adding an end date of 10NOV2020. As this Dexamethasone was not taken for 14 days, please verify it is not a prohibited medication per section 6.5.1 of the protocol. Therefore, please verify it was entered in error.
Feb-16-2021 17:57:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-16-2021 17:57:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> NO End Date:  Nov/10/2020	New Information
Feb-15-2021 11:24:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b) (6)	Query 1: Opened	CLINQUERY: Dexamethasone is

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**Generated By:** (b) (4)

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Time (US & Canada)		(b) (4)		reported as ONGOING since 07NOV2020. However, it is reported that the subject received Vaccination #3 on 01FEB2021. Please verify that the Dexamethasone ended prior to this vaccination and provide an end date as appropriate
Nov-11-2020 10:36:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> YES	Initial Entry

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Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Deleted, Verified**Site No:** 1221**Site Name:** (1221) Center for American Indian Health - Gallup**Subject No:** 12211002**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11

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[Back to Form](#)**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Nov-11-2020 10:41:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Nov-11-2020 10:41:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> CONCOMITANT IMMUNOSU PPRESSIVE THERAPY	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Nov-11-2020 10:41:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry

**4. Medication:**

*Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).*

Date	Location	User	Value	Reason
Nov-17-2020 06:30:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Response satisfies query
Nov-16-2020 23:01:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Deleted per query
Nov-16-2020 06:41:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Opened	CLINQUERY: This is not a prohibited medication per

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				protocol. Please remove from page.
Nov-16-2020 06:24:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Candidate	CLINQUERY: This is not a prohibited medication per protocol. Please remove from page.
Nov-11-2020 10:41:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Remdesivir	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Nov-11-2020 10:41:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> 200	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Nov-11-2020 10:41:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> mg	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Nov-11-2020 10:41:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> ONCE	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Nov-11-2020 10:41:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> INTRAVENOUS	Initial Entry

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**Site Name:** (1221) Center for American Indian Health - Gallup

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**Generated By:** (b) (4)

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**9. Start Date:**

Date	Location	User	Value	Reason
Nov-11-2020 10:41:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Nov/3/2020	Initial Entry

**10. Ongoing?**

Date	Location	User	Value	Reason
Nov-11-2020 10:41:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> NO End Date: Nov/3/2020	Initial Entry

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Generated By: (b) (4)

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Nov-11-2020 10:42:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Nov-11-2020 10:42:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> CONCOMITANT IMMUNOSU PPRESSIVE THERAPY	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Nov-11-2020 10:42:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Nov-17-2020 06:30:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Closed	Response satisfies query
Nov-16-2020 23:02:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Deleted per query
Nov-16-2020 06:42:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Opened	CLINQUERY: This is not a prohibited med. Please remove

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				from page.
Nov-16-2020 06:25:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	Query 1: Candidate	CLINQUERY: This is not a prohibited med. Please remove from page.
Nov-11-2020 10:42:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Remdesivir	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Nov-11-2020 10:42:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> 100	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Nov-11-2020 10:42:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> mg	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Nov-11-2020 10:42:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> QD	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Nov-11-2020 10:42:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> INTRAVENOUS	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
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090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - eCRF  
Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Deleted, Verified

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

Nov-11-2020 10:42:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Nov/4/2020	Initial Entry
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**10. Ongoing?**

Date	Location	User	Value	Reason
Nov-11-2020 10:42:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> NO End Date:  Nov/6/2020	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1221

Subject No: 12211002

Generated By: (b) (4)

Form: RADIATION TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Category:**

Date	Location	User	Value	Reason
Nov-11-2020 10:43:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. What is the treatment Identifier?**

Date	Location	User	Value	Reason
Nov-11-2020 10:43:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Concomitant Non-drug Treatment Pre-specified:**

Date	Location	User	Value	Reason
Nov-11-2020 10:43:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Treatment:**

Date	Location	User	Value	Reason
Nov-11-2020 10:43:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Nov-11-2020 10:43:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Ongoing?**

Date	Location	User	Value	Reason
Nov-11-2020 10:43:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1221

**Subject No:** 12211002

**Generated By:** (b) (4)

**Form:** RADIATION TREATMENT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

Time (US & Canada)				
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090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1221

**Subject No:** 12211002

**Generated By:** (b) (4)

**Form:** TRANSFUSIONS - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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**1. Transfusion Type:**

Date	Location	User	Value	Reason
Nov-11-2020 10:43:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Date of Transfusion:**

Date	Location	User	Value	Reason
Nov-11-2020 10:43:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jane Halpern (b) (4)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** C4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Dec-04-2020 12:08:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Dec/4/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Dec-04-2020 12:08:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Dec-04-2020 12:08:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (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:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

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*I. Date of Visit*

Date	Location	User	Value	Reason
Feb-01-2021 15:16:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> Jan/27/2021	Changed Information
Feb-01-2021 15:15:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> Feb/1/2021	Initial Entry



**Header Text:** C4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form Version:** 10-Dec-2020 02:25

**Site No:** 1221

**Subject No:** 12211002

**Generated By:** (b) (4)

**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit  
Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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*1. Select appropriate response - Is participant willing to return for Vaccination 3?*

Date	Location	User	Value	Reason
Feb-01-2021 15:15:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible per local/national recom- mendations and confirmed to ha- ve received only placebo at Vac- cination 1/2	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1221

**Subject No:** 12211002

**Generated By:** (b) (4)

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-01-2021 15:11:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> Jan/27/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Feb-01-2021 15:11:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1221

**Subject No:** 12211002

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-01-2021 15:18:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> Feb/1/2021	Initial Entry

**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:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

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*I. Consent Was:*

Date	Location	User	Value	Reason
Feb-01-2021 15:18:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Feb/1/2021	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:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Feb-01-2021 15:19:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> Feb/1/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Feb-01-2021 15:19:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Feb-01-2021 15:19:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (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: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-01-2021 15:19:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-01-2021 15:19:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-01-2021 15:27:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-01-2021 15:19:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-01-2021 15:19:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6) [Redacted]	<b>Data Entry:</b> YES Date of Collection: Feb/1/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-01-2021 15:27:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6) [Redacted]	<b>Data Entry:</b> Sample ID: BRJ42L	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (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: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.a Sample ID

Date	Location	User	Value	Reason
Feb-01-2021 15:27:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<u>Data Entry:</u> BRJ42L	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-01-2021 15:27:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<u>Data Entry:</u> Sample ID: BS6ZGG	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-01-2021 15:27:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<u>Data Entry:</u> BS6ZGG	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-01-2021 15:27:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<u>Data Entry:</u> Sample ID: BS6ZGH	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-01-2021 15:27:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<u>Data Entry:</u> BS6ZGH	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (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: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-01-2021 15:20:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-01-2021 15:20:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-01-2021 15:25:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-01-2021 15:20:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-01-2021 15:20:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6) [Redacted]	<b>Data Entry:</b> YES Date of Collection:  Feb/1/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-01-2021 15:25:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6) [Redacted]	<b>Data Entry:</b> Sample ID: BRJ42H	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (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:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

**5.a Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Feb-01-2021 15:25:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> BRJ42H	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1221

Subject No: 12211002

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Feb-01-2021 15:20:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Feb-01-2021 15:20:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Feb-01-2021 15:20:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Feb-01-2021 15:20:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> Feb/1/2021 12:43	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Feb-01-2021 15:20:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Feb-01-2021 15:20:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> RIGHT	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1221

Subject No: 12211002

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Time (US & Canada)				
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7. Route:

Date	Location	User	Value	Reason
Feb-01-2021 15:20:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-01-2021 15:20:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-01-2021 15:20:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-01-2021 15:20:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 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-01-2021 15:20:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6) [Redacted]	<u>Data Entry:</u> YES	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** V102\_VAX4

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1221

**Subject No:** 12211002

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-22-2021 17:48:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> Feb/22/2021	Initial Entry

Header Text: C4591001

Visit: V102\_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1221

Site Name: (1221) Center for American Indian Health - Gallup

Subject No: 12211002

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-22-2021 17:48:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-22-2021 17:48:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-22-2021 17:50:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-22-2021 17:48:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-22-2021 17:48:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6) [Redacted]	<b>Data Entry:</b> YES Date of Collection: Feb/22/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-22-2021 17:50:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6) [Redacted]	<b>Data Entry:</b> Sample ID: BRJ43Y	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (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:** 1221

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject No:** 12211002

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-22-2021 17:50:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<u>Data Entry:</u> BRJ43Y	Initial Entry

Header Text: C4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1221

Subject No: 12211002

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Feb-22-2021 17:49:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Feb-22-2021 17:49:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Feb-22-2021 17:49:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Feb-22-2021 17:49:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> Feb/22/2021 16:44	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Feb-22-2021 17:49:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Feb-22-2021 17:49:38 (UTC-07:00) Mountain	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> RIGHT	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

Header Text: C4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1221

Subject No: 12211002

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1221) Center for American Indian Health - Gallup

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

Time (US & Canada)				
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7. Route:

Date	Location	User	Value	Reason
Feb-22-2021 17:49:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-22-2021 17:49:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-22-2021 17:49:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-22-2021 17:49:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 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-22-2021 17:49:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6) [Redacted]	<u>Data Entry:</u> YES	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)



**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1221

**Subject No:** 12211002

**Generated By:** (b) (4)

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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**1. Subject Status**

Date	Location	User	Value	Reason
Dec-04-2020 12:08:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Oct-15-2020 13:17:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Oct-14-2020 12:25:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Dec-04-2020 12:08:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Dec/4/2020	Initial Entry
Oct-15-2020 13:17:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/13/2020	Initial Entry
Oct-14-2020 12:25:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/13/2020	Initial Entry

090177e196ae4040\Final\Final On: 01-Apr-2021 05:34 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1221

**Subject No:** 12211002

**Generated By:** (b) (4)

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

**Form Status:** Data Complete, Signed, Verified

**Site Name:** (1221) Center for American Indian Health - Gallup

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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*I. Casebook Signature*

Date	Location	User	Value	Reason
Mar-08-2021 18:22:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry
Mar-08-2021 18:22:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4),(b)(6)	<b>Data Entry:</b>	Changed Information
Nov-17-2020 18:11:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	(b)(4), (b)(6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry