

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[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: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/17/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11671009]
2.	Birth Date:	(b) (6) /1981
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Aug/17/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Aug/17/2020
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: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Allergic Rhinitis]
	Start Date:	Jun/7/2016
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Anxiety]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Low Back Pain]
	Start Date:	Jul/9/2018
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypothyroidism]
	Start Date:	Apr/UNK/2011
	Ongoing:	YES

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Panic Attacks]
	Start Date:	Jul/24/2019
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hysterectomy]
	Start Date:	Jan/31/2020
	Ongoing:	NO End Date: Jan/31/2020
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[S/p laparoscopic sleeve gastrectomy]
	Start Date:	May/10/2018
	Ongoing:	NO End Date: May/10/2018
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Obesity]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/17/2020
2.	Weight:	[261.01]
3.	Unit:	LB
4.	Height:	[70.0]
5.	Unit:	in
6.	Body Mass Index:	[37.4]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.1]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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

Lab Urinalysis

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

Lab Result

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

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/17/2020
2.	Randomization Number:	[50474]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/17/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BN6F4T]
5.b	Sample ID	[BN6F4V]
5.c	Sample ID	[BN6F4W]
5.d	Sample ID	[BL9ZBT]
5.e	Sample ID	[BL9ZBV]

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/17/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BN6FHC]
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090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/17/2020 15:51
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

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

eCRF Audit Trail History

Date of Visit

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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

Lab Urinalysis

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

Lab Result

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

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/9/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BN6FNT]
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090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/9/2020 11:53
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

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Oct/7/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/7/2020
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	[BM9BV1]
5.b	Sample ID	[BLB0Z0]
5.c	Sample ID	[BLB0Z1]

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Feb/03/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/3/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
on Feb/03/2021

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Feb/3/2021
2.	Date of First Symptom Started:	Jan/26/2021
3.	Symptoms Ongoing?	NO
	Date of Last Symptom Resolved:	Feb/7/2021

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

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Feb/03/2021

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

4.i	Symptoms:	VOMITING
	Was symptom present?	NO

Symptoms - Other

5.a	Symptoms - Other Text:	[Fatigue]
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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Feb/3/2021	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Feb/03/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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[Form Audit Trail](#)

Microbiology Specimen

1.	Actual Date of Collection:	Feb/3/2021
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 DIAGNOSTICS ID NOW COVID-19
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[]
9.	Trade Name Other, Specify:	[]

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Feb/03/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Subject came into the office for s 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 Feb/03/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/3/2021
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	[BR1DSX]
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090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Feb/03/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete, Frozen**Site No:** 1167**Site Name:** (1167) Holston Medical Group**Subject No:** 11671009**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23**eCRF Audit Trail History****Health Care Utilization**

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

Health Care Utilization Other

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

Health Care Utilization

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT
on Feb/03/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Respiratory Treatment

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

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS
on Feb/03/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [Mycoplasma pneumonia] Date of Diagnosis: Jan/26/2021
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: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	Category of Clinical Event :	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Feb/03/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	Not Applicable _____	Comments
2.	Subcategory of Clinical Event:	Not Applicable _____	Comments
3.	Was a diagnosis obtained?	Not Applicable _____	Comments
4.	Toxicity Grade:	Not Applicable _____	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 30-Jul-2020 21:27

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	
					Not Done	Not Done	Not Done	

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Feb/03/2021

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

Lab Chemistry Details

1.	Lab Panel:	Not Done _____	Comments
2.	Laboratory Name and Address	Not Done _____ []	Comments
3.	Collection Date:	Not Done _____ //	Comments
4.	Specimen Type:	Not Done _____	Comments

Lab Result

5.a	Sponsor ID:	Not Done _____ []	Comments
	Test:	C Reactive Protein_PX329	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Feb/03/2021

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.b	Sponsor ID:	Not Done _____ []	Comments
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments
5.c	Sponsor ID:	Not Done _____ []	Comments
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Feb/03/2021

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.d	Sponsor ID:	Not Done _____ []	Comments
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments
5.e	Sponsor ID:	Not Done _____ []	Comments
	Test:	Bilirubin_PX21	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Feb/03/2021

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.f	Sponsor ID:	Not Done _____ []	Comments
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments
5.g	Sponsor ID:	Not Done _____ []	Comments
	Test:	Creatinine_PX48	
	Result:	Not Done _____ []	Comments
	Not Done:	Not Done _____	Comments
	LNMT	Not Done _____ Low [] High [] Unit	Comments

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	HEMATOLOGY	Holston Medical Group 105 West Stone Drive Kingsport, TN 37660	Feb/3/2021	BLOOD	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					1	Hemoglobin_PX1	14.1	
					2	Hematocrit_PX2	42.5	
					3	Erythrocytes_PX3	4.81	
					5	Platelets_PX5	192	
					7	Leukocytes_PX7	5.9	
					608	Neutrophils_PX608	73.0	
					609	Eosinophils_PX609	[]	
					612	Monocytes_PX612	[]	
					610	Basophils_PX610	[]	
611	Lymphocytes_PX611	19.40						

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology on Feb/03/2021

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Laboratory Data Hematology

1.	Lab Panel:	HEMATOLOGY
2.	Laboratory Name and Address	[Holston Medical Group 105 West Stone Drive Kingsport, TN 37660]
3.	Collection Date:	Feb/3/2021
4.	Specimen Type:	BLOOD

Lab Result

5.a	Sponsor ID:	[1]
	Test:	Hemoglobin_PX1
	Result:	[14.1]
	Not Done:	
	LNMT	Low [11.5] High [15.5] Unit g/dL
5.b	Sponsor ID:	[2]
	Test:	Hematocrit_PX2
	Result:	[42.5]
	Not Done:	
	LNMT	Low [34.5] High [46.5] Unit %

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Feb/03/2021

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.c	Sponsor ID:	[3]
	Test:	Erythrocytes_PX3
	Result:	[4.81]
	Not Done:	
	LNMT	Low [3.89] High [5.33] Unit 10^9/L
5.d	Sponsor ID:	[5]
	Test:	Platelets_PX5
	Result:	[192]
	Not Done:	
	LNMT	Low [140] High [400] Unit 10^12/L
5.e	Sponsor ID:	[7]
	Test:	Leukocytes_PX7
	Result:	[5.9]
	Not Done:	
	LNMT	Low [3.0] High [10.0] Unit 10^12/L

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Feb/03/2021

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.f	Sponsor ID:	[608]
	Test:	Neutrophils_PX608
	Result:	[73.0]
	Not Done:	
	LNMT	Low [43.0] High [77.0] Unit %
5.g	Sponsor ID:	[609]
	Test:	Eosinophils_PX609
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.h	Sponsor ID:	[612]
	Test:	Monocytes_PX612
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit

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Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Feb/03/2021

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.i	Sponsor ID:	[610]
	Test:	Basophils_PX610
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.j	Sponsor ID:	[611]
	Test:	Lymphocytes_PX611
	Result:	[19.40]
	Not Done:	
	LNMT	Low [18.0] High [40.0] Unit %

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 30-Jul-2020 21:27

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	Date:	Vital Signs Details			Form Instance					
1.	Feb/3/2021	<table border="1"><thead><tr><th>Record Identifier:</th><th>Systolic:</th><th>Diastolic:</th></tr></thead><tbody><tr><td>1</td><td>126</td><td>88</td></tr></tbody></table>	Record Identifier:	Systolic:	Diastolic:	1	126	88	Repeating Pages	
Record Identifier:	Systolic:	Diastolic:								
1	126	88								

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Feb/03/2021

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Vital Signs

1.	Date:	Feb/3/2021
----	-------	------------

Vital Signs Details

2.a	Record Identifier:	1	
	Systolic:	[126]	
	Diastolic:	[88]	
	Respiratory Rate in respirations/minute:	Not Done []	Comments
	Heart Rate in beats/minute:	[76]	

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 30-Jul-2020 21:28

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	Date:	Vital Signs Details		Form Instance
1.	Feb/3/2021	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	98.0	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Feb/03/2021

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Vital Signs

1.	Date:	Feb/3/2021
----	-------	------------

Vital Signs Details

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[98.0]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS
on Feb/03/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Oxygenation Parameters

1.	Date Time of Assessment:	Not Done _____ //	Comments
2.	Arterial Blood Gases PaO2 (mmHg):	Not Done _____ []	Comments
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Done _____ []	Comments

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
on Feb/03/2021

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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[eCRF Audit Trail History](#)

Concomitant Medications

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

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Feb/3/2021	CHEST	X-RAY	NORMAL	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING
on Feb/03/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Imaging

1.	Date of Assessment:	Feb/3/2021
2.	Location of Assessment:	CHEST
3.	Type of Imaging Exam:	X-RAY
4.	Assessment:	NORMAL

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
Visit on Mar/08/2021

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/8/2021
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 Mar/08/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/8/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR1DX7]
5.b	Sample ID	[BNVSRK]
5.c	Sample ID	[BNVSRL]

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Unplanned Assessments

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/7/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Disposition - Follow-Up

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Acute Cholecystitis	Aug/21/2020 UNK:UNK	NO End Date Time: Aug/22/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Cholelithiasis	Aug/21/2020 UNK:UNK	NO End Date Time: Aug/22/2020 UNK:UNK	Repeating Pages
3. DELETED	ADVERSE EVENT	3	Mycoplasma pneumoniae	Jan/26/2021 UNK:UNK	YES	Repeating Pages
4.	ADVERSE EVENT	4	Acute hepatitis	Feb/25/2021 UNK:UNK	YES	Repeating Pages

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Acute Cholecystitis]
4.	Start Date Time:	Aug/21/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/22/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Cholelithiasis and sudden weight loss due to baratric surgery 2018]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020328447]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Cholelithiasis]
4.	Start Date Time:	Aug/21/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/22/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Sudden weight loss due to bariatric surgery]

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED WITH SEQUELAE
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

*** THIS REPEATING FORM HAS BEEN DELETED ***

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Mycoplasma pneumonia]
4.	Start Date Time:	Jan/26/2021 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Atypical bacteria]

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

*** THIS REPEATING FORM HAS BEEN DELETED ***

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Answered Queries

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Acute hepatitis]
4.	Start Date Time:	Feb/25/2021 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	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
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

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Answered Queries

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [suspected due to doxycycline and Zithromax]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERING/RESOLVING
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021241196]

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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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	[]

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	Fluzone (Influenza vaccine)	Oct/6/2020	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Fluzone (Influenza vaccine)]
5.	Date:	Oct/6/2020

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1. DELETED	1	CORTICOSTEROIDS	NO	Dexamethasone sodium phosphate	2	Repeating Pages

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Data Complete, Deleted, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

*** THIS REPEATING FORM HAS BEEN DELETED ***

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Concomitant Medications

1.	What is the medication identifier?	[1]
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 sodium phosphate]
5.	Dose:	[2]
6.	Dose Unit:	mL
7.	Dose Frequency:	ONCE
8.	Route:	INTRAMUSCULAR
9.	Start Date:	Feb/3/2021
10.	Ongoing?	NO End Date: Feb/3/2021

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Lab Urinalysis

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

Lab Result

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

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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?	

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Contact Outcome

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/15/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Dec/16/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Dec/16/2020
----	--------------	--

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation/Death :	Dec/16/2020
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001**Visit:** V101_VAX3**Form Version:** 10-Dec-2020 02:23**Site No:** 1167**Subject No:** 11671009**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1167) Holston Medical Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23**Form Comments**
eCRF Audit Trail History**Lab Urinalysis**

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

Lab Result

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/16/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BM9BJ3]
5.b	Sample ID	[BSGHG5]
5.c	Sample ID	[BSGHG6]

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Dec/16/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BM9BJ2]
-----	-----------	----------

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Dec/16/2020 13:38
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Dec/15/2020
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Jan/4/2021
2.	Erroneous Visit	

Header Text: c4591001**Visit:** V102_VAX4**Form Version:** 10-Dec-2020 02:23**Site No:** 1167**Subject No:** 11671009**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1167) Holston Medical Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23**[Form Comments](#)**
[eCRF Audit Trail History](#)**Lab Urinalysis**

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

Lab Result

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

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

eCRF Audit Trail History

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/4/2021
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	[BM9BJV]
-----	-----------	----------

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/4/2021 13:33
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Data Complete, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Contact Outcome

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

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Contact Outcome

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

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Disposition - Treatment

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/7/2020

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: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[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: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
David Morin	Approved	Mar-09-2021 15:33:47 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, DavidMorin, 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.

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
Form	Aug-17-2020 15:41:38 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
Form	Aug-17-2020 15:47:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
1	Aug-17-2020 15:47:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
2	Aug-17-2020 15:47:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
3	Aug-17-2020 15:47:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
4	Aug-17-2020 15:47:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
5	Aug-17-2020 15:47:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
6.a	Aug-17-2020 15:47:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
6.a	Aug-17-2020 15:47:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
6.a	Aug-17-2020 15:47:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
Form	Sep-10-2020 17:43:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject has had a hysterectomy _____ Not Applicable
Form	Sep-10-2020 08:14:55 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject has had a hysterectomy _____ Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
1	Sep-10-2020 17:43:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject has had a hysterectomy Not Applicable
1	Sep-10-2020 08:14:55 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject has had a hysterectomy Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
2	Sep-10-2020 17:43:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject has had a hysterectomy Not Applicable
2	Sep-10-2020 08:14:55 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject has had a hysterectomy Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
3	Sep-10-2020 17:43:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject has had a hysterectomy Not Applicable
3	Sep-10-2020 08:14:55 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject has had a hysterectomy Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
4	Sep-10-2020 17:43:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject has had a hysterectomy Not Applicable
4	Sep-10-2020 08:14:55 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject has had a hysterectomy Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
5	Sep-10-2020 17:43:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject has had a hysterectomy Not Applicable
5	Sep-10-2020 08:14:55 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject has had a hysterectomy Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
6.a	Sep-10-2020 17:43:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject has had a hysterectomy Not Applicable
6.a	Sep-10-2020 08:14:55 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject has had a hysterectomy Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
6.a	Sep-10-2020 17:43:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject has had a hysterectomy Not Applicable
6.a	Sep-10-2020 08:14:55 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject has had a hysterectomy Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:27

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
6.a	Sep-10-2020 17:43:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject has had a hysterectomy Not Applicable
6.a	Sep-10-2020 08:14:55 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Subject has had a hysterectomy Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Feb/03/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
Form	Feb-03-2021 11:47:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Feb/03/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
1	Feb-03-2021 11:47:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Feb/03/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
2	Feb-03-2021 11:47:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
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Generated By: (b) (4)

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Item	Date	User	Comment
3	Feb-03-2021 11:47:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
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Subject Initials: ---

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Item	Date	User	Comment
4	Feb-03-2021 11:47:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
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Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
5	Feb-03-2021 11:47:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Feb/03/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1167

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Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
6	Feb-03-2021 11:47:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments on Feb/03/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
Form	Feb-03-2021 11:47:37 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments on Feb/03/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
1	Feb-03-2021 11:47:37 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments on Feb/03/2021

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Subject No: 11671009

Subject Initials: ---

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Item	Date	User	Comment
2	Feb-03-2021 11:47:37 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments on Feb/03/2021

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
5.a	Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

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Item	Date	User	Comment
5.a	Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

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Site No: 1167

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Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
5.b	Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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Form Status: Data Complete, Frozen

Site No: 1167

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Item	Date	User	Comment
5.b	Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

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Item	Date	User	Comment
5.b	Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

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Item	Date	User	Comment
5.b	Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
5.c	Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
5.c	Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

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Item	Date	User	Comment
5.c	Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

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Item	Date	User	Comment
5.c	Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1167

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Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
5.d	Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
5.d	Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

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Item	Date	User	Comment
5.d	Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

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Item	Date	User	Comment
5.d	Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

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Item	Date	User	Comment
5.e	Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

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Item	Date	User	Comment
5.e	Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

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Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
5 f	Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
5 f	Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
5 f	Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
5 f	Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

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Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
5.g	Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1167

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Subject No: 11671009

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Generated By: (b) (4)

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Item	Date	User	Comment
5.g	Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
5.g	Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
5.g	Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Comments
on Feb/03/2021

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
2.a	Feb-03-2021 11:52:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Feb/03/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
Form	Feb-03-2021 11:52:55 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Feb/03/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
1	Feb-03-2021 11:52:55 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Feb/03/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
2	Feb-03-2021 11:52:55 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Feb/03/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

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Item	Date	User	Comment
3	Feb-03-2021 11:52:55 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
Form	Feb-03-2021 11:53:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1167

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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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Form Status: Data Complete, Frozen

Site No: 1167

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Header Text: c4591001

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Item	Date	User	Comment
4	Feb-03-2021 11:53:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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Site No: 1167

Site Name: (1167) Holston Medical Group

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Generated By: (b) (4)

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Item	Date	User	Comment
5	Feb-03-2021 11:53:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
6	Feb-03-2021 11:53:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
Form	Dec-16-2020 13:28:55 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
Form	Dec-16-2020 13:30:15 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	patient is no WOCBP _____ Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

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Item	Date	User	Comment
1	Dec-16-2020 13:30:15 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	patient is no WOCBP <hr/> Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
2	Dec-16-2020 13:30:15 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	patient is no WOCBP <hr/> Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:23

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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Site Name: (1167) Holston Medical Group

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Item	Date	User	Comment
3	Dec-16-2020 13:30:15 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	patient is no WOCBP <hr/> Not Applicable

Header Text: c4591001

Visit: V101_VAX3

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Site Name: (1167) Holston Medical Group

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Item	Date	User	Comment
4	Dec-16-2020 13:30:15 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	patient is no WOCBP <hr/> Not Applicable

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Item	Date	User	Comment
5	Dec-16-2020 13:30:15 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	patient is no WOCBP <hr/> Not Applicable

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Item	Date	User	Comment
6.a	Dec-16-2020 13:30:15 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	patient is no WOCBP <hr/> Not Applicable

Header Text: c4591001

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Site Name: (1167) Holston Medical Group

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Item	Date	User	Comment
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Header Text: c4591001

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Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
6.a	Dec-16-2020 13:30:15 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	patient is no WOCBP <hr/> Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
Form	Jan-04-2021 12:01:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
1	Jan-04-2021 12:01:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
2	Jan-04-2021 12:01:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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3	Jan-04-2021 12:01:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Visit: V102_VAX4

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Item	Date	User	Comment
6.a	Jan-04-2021 12:01:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
6.a	Jan-04-2021 12:01:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:23

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Item	Date	User	Comment
6.a	Jan-04-2021 12:01:05 (UTC-05:00) Eastern 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: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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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
David Morin	Approved	Mar-09-2021 15:33:47 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, DavidMorin, 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-09-2021 08:21:16 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Emily Morawski	Approved	Feb-08-2021 16:40:43 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, EmilyMorawski, 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 13:11:52 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (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: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Emily Morawski	Approved	Jan-21-2021 13:13:37 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Dec-16-2020 13:27:02 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Emily Morawski	Approved	Nov-17-2020 07:50:47 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Nov-16-2020 14:50:41 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

David Morin	Approved	Nov-02-2020 09:05:41 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (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: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Affidavit:

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

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

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

(b) (6)	N/A	Nov-02-2020 08:32:13 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

David Morin	Approved	Oct-30-2020 10:40:41 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

(b) (6)	N/A	Oct-30-2020 10:25:56 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Emily Morawski	Approved	Oct-22-2020 07:55:19 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (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: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Affidavit:

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

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-17-2020 15:05:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-17-2020 15:05:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Aug-17-2020 15:05:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Aug/17/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Aug-17-2020 15:05:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11671009	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-17-2020 15:05:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1981	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-17-2020 15:06:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-17-2020 15:06:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-17-2020 15:06:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Aug-17-2020 15:40:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/17/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-17-2020 15:41:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/17/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-17-2020 15:41:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-17-2020 15:41:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

1.a

Date	Location	User	Value	Reason
Aug-17-2020 15:42:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Allergic Rhinitis Start Date: Jun/7/2016 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 15:42:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-17-2020 15:42:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Allergic Rhinitis	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 15:42:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jun/7/2016	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 15:42:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.b

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Date	Location	User	Value	Reason
Aug-17-2020 15:43:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 2 : Medical History Term: Anxiety Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 15:43:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-17-2020 15:43:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Anxiety	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 15:43:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 15:43:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
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090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Aug-17-2020 15:43:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Te Low Back P rm: ain Start Date: Jul/9/2018 Ongoing: YES	Initial Entry
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I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 15:43:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-17-2020 15:43:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Low Back Pain	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 15:43:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jul/9/2018	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 15:43:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-17-2020 15:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History T Hypothyroidi erm: sm	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

			Start Date:	Apr/UNK/2011	
			Ongoing:	YES	

I.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 15:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-17-2020 15:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hypothyroidism	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 15:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Apr/UNK/2011	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 15:43:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Aug-17-2020 15:44:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: Panic Attacks Start Date: Jul/24/2019 Ongoing: YES	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

I.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 15:44:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-17-2020 15:44:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Panic Attacks	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 15:44:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jul/24/2019	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 15:44:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Aug-17-2020 15:44:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History Te Hysterectom rm: y Start Date: Jan/31/2020 Ongoing: NO End Date: Jan/31/20 20	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

I.f Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 15:44:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Aug-17-2020 15:44:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hysterectomy	Initial Entry

I.f Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 15:44:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/31/2020	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 15:44:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Jan/31/2020	Initial Entry

I.g

Date	Location	User	Value	Reason
Aug-17-2020 15:45:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N umber: 7 Medical His tory Term: S/p laparoscopic sle eve gastrectomy Start Date: May/10/2018	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

			Ongoing: NO End Date: May/10/2018	
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I.g Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 15:45:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Aug-17-2020 15:45:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: S/p laparoscopic sleeve gastrectom y	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 15:45:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: May/10/2018	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 15:45:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: May/10/2018	Initial Entry

I.h

Date	Location	User	Value	Reason
Aug-17-2020 15:46:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number 8 :	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

			Medical History T Obesity erm: Start Date: UNK/UNK/2000 Ongoing: YES	
Aug-17-2020 15:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 8 : Medical History T Obesity erm: Start Date: UNK/UNK/2000 Ongoing:	Initial Entry

1.h Line/MH Number:

Date	Location	User	Value	Reason
Aug-17-2020 15:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Aug-17-2020 15:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Obesity	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Aug-17-2020 15:46:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2000	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Aug-17-2020 15:46:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date:

Date	Location	User	Value	Reason
Aug-17-2020 15:46:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aug/17/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-17-2020 15:46:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 261.01	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-17-2020 15:46:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-17-2020 15:46:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 70.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-17-2020 15:46:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-17-2020 15:46:50 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 37.4	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Time (US & Canada)				
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7.a

Date	Location	User	Value	Reason
Aug-17-2020 15:46:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 98.1 Temperature Unit: F Temperature Locat ORAL CAVI ion:: TY	Initial Entry
Aug-17-2020 15:46:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 98.1 Temperature Unit: Temperature Location::	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-17-2020 15:46:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-17-2020 15:46:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.1	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-17-2020 15:46:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Aug-17-2020 15:46:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Lab Panel:

Date	Location	User	Value	Reason
Aug-17-2020 15:47:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-17-2020 15:47:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-17-2020 15:47:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-17-2020 15:47:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-17-2020 15:47:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Aug-17-2020 15:47:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Result:: Not Done::	Initial Entry Not Applicable Not Applicable Not Applicable Not Applicable
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-17-2020 15:47:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-17-2020 15:47:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-17-2020 15:47:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Aug-17-2020 15:47:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-17-2020 15:47:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/17/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-17-2020 15:47:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 50474	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Data Origin

Date	Location	User	Value	Reason
Aug-17-2020 15:47:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-17-2020 15:47:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-17-2020 15:49:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-17-2020 15:47:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-17-2020 15:47:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-17-2020 15:49:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN6F4T	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.a Sample ID

Date	Location	User	Value	Reason
Aug-17-2020 15:49:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BN6F4T	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-17-2020 15:50:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BN6F4V	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-17-2020 15:50:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BN6F4V	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-17-2020 15:50:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BN6F4W	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-17-2020 15:50:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BN6F4W	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-17-2020 15:50:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BL9ZBT	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.d Sample ID

Date	Location	User	Value	Reason
Aug-17-2020 15:50:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BL9ZBT	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-17-2020 15:50:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BL9ZBV	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-17-2020 15:50:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BL9ZBV	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (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: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Data Origin

Date	Location	User	Value	Reason
Aug-17-2020 15:48:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-17-2020 15:48:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-17-2020 15:49:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-17-2020 15:48:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-17-2020 15:48:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-17-2020 15:49:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN6FHC	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (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: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.a Sample ID

Date	Location	User	Value	Reason
Aug-17-2020 15:49:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN6FHC	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-17-2020 15:51:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-17-2020 15:51:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-17-2020 15:51:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-17-2020 15:51:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/17/2020 15:51	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-17-2020 15:51:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-17-2020 15:51:54 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Time (US & Canada)				
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7. Route:

Date	Location	User	Value	Reason
Aug-17-2020 15:51:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-17-2020 15:51:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 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
Aug-17-2020 15:51:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-17-2020 15:52:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E-DIA RY NOT COLLECTED FOR THI S SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-10-2020 08:13:42 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/9/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date:

Date	Location	User	Value	Reason
Sep-10-2020 08:14:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/9/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-10-2020 08:14:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 97.9 Temperature Unit: F Temperature Location:: EAR	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-10-2020 08:14:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-10-2020 08:14:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.9	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-10-2020 08:14:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Sep-10-2020 08:14:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EAR	Initial Entry
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Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-10-2020 17:43:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-10-2020 08:14:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-10-2020 17:43:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-10-2020 08:14:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-10-2020 17:43:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-10-2020 08:14:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-10-2020 17:43:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-10-2020 08:14:55	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	Not Done	
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5. Specimen Type:

Date	Location	User	Value	Reason
Sep-10-2020 17:43:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-10-2020 08:14:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-10-2020 17:43:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Done Result:: Not Applicable Not Done:: Not Applicable	Initial Entry
Sep-10-2020 08:14:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-10-2020 17:43:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Sep-10-2020 08:14:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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6.a Test:

Date	Location	User	Value	Reason
Sep-10-2020 08:14:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-10-2020 17:43:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-10-2020 08:14:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-10-2020 17:43:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Sep-10-2020 08:14:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (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: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Data Origin

Date	Location	User	Value	Reason
Sep-10-2020 08:15:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-10-2020 08:15:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-10-2020 08:15:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-10-2020 08:15:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-10-2020 08:15:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/9/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-10-2020 08:15:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BN6FNT	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (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: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.a Sample ID

Date	Location	User	Value	Reason
Sep-10-2020 08:15:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BN6FNT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-10-2020 08:16:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-10-2020 08:16:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-10-2020 08:16:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-10-2020 08:16:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/9/2020 11:53	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-10-2020 08:16:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-10-2020 08:16:31 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Time (US & Canada)

(b) (4)

7. Route:

Date	Location	User	Value	Reason
Sep-10-2020 08:16:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-10-2020 08:16:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 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
Sep-10-2020 08:16:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-07-2020 13:08:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/7/2020	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, Locked, Frozen, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Data Origin

Date	Location	User	Value	Reason
Oct-07-2020 13:08:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-07-2020 13:08:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-07-2020 13:11:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-07-2020 13:08:39 (UTC-05:00) Eastern 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-07-2020 13:08:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/7/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-07-2020 13:11:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM9BV1	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.a Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 13:11:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BM9BV1	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-07-2020 13:11:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BLB0Z0	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 13:11:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BLB0Z0	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-07-2020 13:11:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BLB0Z1	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-07-2020 13:11:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BLB0Z1	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Feb/03/2021**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1167**Site Name:** (1167) Holston Medical Group**Subject No:** 11671009**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23[Back to Form](#)**1. Date of Visit**

Date	Location	User	Value	Reason
Feb-03-2021 11:45:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-03-2021 11:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Feb-03-2021 11:43:55 (UTC-05:00) Eastern 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.
Feb-03-2021 11:43:55 (UTC-05:00) Eastern 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.
Feb-03-2021 11:43:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/3/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Feb-03-2021 11:43:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete, Frozen**Site No:** 1167**Site Name:** (1167) Holston Medical Group**Subject No:** 11671009**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Feb-03-2021 11:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/3/2021	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Feb-15-2021 08:07:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Feb-09-2021 08:21:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-09-2021 08:21:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/26/2021	New Information
Feb-08-2021 15:59:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: There is a discrepancy between the MYCOPLASMA PNEUMONIA start date: 26Jan2021 on the AE CRF LOG and Date of First Symptom Started: 02Feb2021 on the CRF SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 form. Please review and update as appropriat
Feb-03-2021 11:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/2/2021	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Mar-05-2021 13:14:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Feb/7/2021	New Information
Feb-03-2021 11:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Feb-03-2021 11:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Feb-03-2021 11:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Feb-03-2021 11:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Feb-03-2021 11:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: YES	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete, Frozen**Site No:** 1167**Site Name:** (1167) Holston Medical Group**Subject No:** 11671009**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23**4.b Symptoms:**

Date	Location	User	Value	Reason
Feb-03-2021 11:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Feb-03-2021 11:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Feb-03-2021 11:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: YES	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Feb-03-2021 11:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Feb-03-2021 11:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.d

Date	Location	User	Value	Reason
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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete, Frozen**Site No:** 1167**Site Name:** (1167) Holston Medical Group**Subject No:** 11671009**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23

Feb-03-2021 11:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry
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4.d Symptoms:

Date	Location	User	Value	Reason
Feb-03-2021 11:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Feb-03-2021 11:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Feb-03-2021 11:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms NEW OR INCREASE : D MUSCLE PAIN Symptom NO Present:	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Feb-03-2021 11:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Feb-03-2021 11:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

4.f

Date	Location	User	Value	Reason
Feb-03-2021 11:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms NEW LOSS OF TAS : TE OR SMELL Symptom NO Present:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Feb-03-2021 11:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SME LL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Feb-03-2021 11:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Feb-03-2021 11:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom NEW OR INCREASE s: D SORE THROAT Symptom NO Present:	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

4.g Symptoms:

Date	Location	User	Value	Reason
Feb-03-2021 11:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SORE TH ROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Feb-03-2021 11:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Feb-03-2021 11:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Feb-03-2021 11:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Feb-03-2021 11:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Feb-03-2021 11:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITING Symptom Present: NO	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

4.i Symptoms:

Date	Location	User	Value	Reason
Feb-03-2021 11:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Feb-03-2021 11:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-03-2021 11:44:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms - Other: Fatigue	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Feb-03-2021 11:44:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Fatigue	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail
on Feb/03/2021

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Date	Location	User	Value	Reason
Feb-03-2021 11:45:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Feb/03/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Feb-03-2021 11:45:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/3/2021	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Feb-03-2021 11:45:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWABBED MATERIAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Feb-03-2021 11:45:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Feb-03-2021 11:45:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDR OME CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Feb-03-2021 11:45:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TES T	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Feb-03-2021 11:45:05 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ABBOTT DIAGNOSTICS ID NO	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Feb/03/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Time (US & Canada)			W COVID-19	
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7. Test Result:

Date	Location	User	Value	Reason
Feb-03-2021 11:45:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEGATIVE	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

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: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Data Origin

Date	Location	User	Value	Reason
Feb-03-2021 11:45:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-03-2021 11:45:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-03-2021 11:46:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Feb-03-2021 11:46:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Feb-03-2021 11:46:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-03-2021 11:46:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

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: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Feb-03-2021 11:45:17 (UTC-05:00) Eastern 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-03-2021 11:45:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/3/2021	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Feb-03-2021 11:46:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Subject came into the office for s s wab	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit
on Feb/03/2021**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:** 1167**Site Name:** (1167) Holston Medical Group**Subject No:** 11671009**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-03-2021 11:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-03-2021 11:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-03-2021 11:45:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-03-2021 11:45:37 (UTC-05:00) Eastern 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-03-2021 11:45:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/3/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-03-2021 11:45:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR1DSX	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

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: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.a Sample ID

Date	Location	User	Value	Reason
Feb-03-2021 11:45:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BR1DSX	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Feb/03/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1.a

Date	Location	User	Value	Reason
Feb-03-2021 11:46:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIA LIST Occurrence of Visits o NO r Contacts:	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-03-2021 11:46:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-03-2021 11:46:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.b

Date	Location	User	Value	Reason
Feb-03-2021 11:46:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practition EMERGENC er: Y ROOM Occurrence of Visi NO ts or Contacts:	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Feb/03/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

I.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-03-2021 11:46:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-03-2021 11:46:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.c

Date	Location	User	Value	Reason
Feb-03-2021 11:46:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-03-2021 11:46:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-03-2021 11:46:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.d

Date	Location	User	Value	Reason
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090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Feb/03/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Feb-03-2021 11:46:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: YES Number of Visits or Contacts: 1	Initial Entry
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1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-03-2021 11:46:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-03-2021 11:46:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Number of Visits or Contacts: 1	Initial Entry

1.e

Date	Location	User	Value	Reason
Feb-03-2021 11:46:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO :	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Feb/03/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete, Frozen**Site No:** 1167**Site Name:** (1167) Holston Medical Group**Subject No:** 11671009**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Feb-03-2021 11:46:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-03-2021 11:46:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Feb-03-2021 11:46:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTHE R Occurrence of Visits or C NO ontacts:	Initial Entry

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-03-2021 11:46:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-03-2021 11:46:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Has the subject been hospitalized due to potential COVID-19 illness?

Date	Location	User	Value	Reason
Feb-03-2021 11:46:44	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Feb/03/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

(UTC-05:00) Eastern
Time (US & Canada)

(b) (4)

NO

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: RESPIRATORY TREATMENT - eCRF Audit Trail History on Feb/03/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Feb-03-2021 11:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Feb-03-2021 11:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Feb-03-2021 11:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Feb-03-2021 11:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Feb-03-2021 11:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
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090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History on Feb/03/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Feb-03-2021 11:47:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - eCRF Audit Trail History on Feb/03/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Feb-03-2021 11:47:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNES S	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Feb-08-2021 15:59:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Closed	Response satisfies query
Feb-08-2021 15:37:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Feb-08-2021 08:32:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Feb-08-2021 08:32:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Feb-08-2021 08:32:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Respiratory Illness Diagnosis:</i> Mycoplasma pneumonia Date of Diagnosis: Jan/26/2021	Changed Information
Feb-05-2021 16:31:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Opened	Clin: Please consider in response to "Was a diagnosis obtained for Potential COVID-19 Illness" entering MYCOPLASMA

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History
on Feb/03/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

				PNEUMONIA.
Feb-05-2021 16:29:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Per Prot Section 8.3.7., COVID-19 related MYCOPLASMA PNEUMONIA does not qualify as AE and please should be documented only on the COVID-19 CRF ILLNESS DETAILS form as MYCOPLASMA PNEUMONIA and should not be captured on the AE CRF page
Feb-03-2021 11:47:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-03-2021 11:47:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Feb/03/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Feb-03-2021 11:47:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Feb-03-2021 11:47:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Feb-03-2021 11:47:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-03-2021 11:47:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Lab Panel:

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			Not Done::	Not Done
			Lab Normal Range:	Not Done

5.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.b Sponsor ID:

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			Test::	Not Done	
				ne	
			Result::	Not Done	
				ne	
			Not Done::	Not Done	
				ne	
			Lab Normal Range:	Not Done	
				ne	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.c Sponsor ID:

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.d

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			Test::	Not Done	
				ne	
			Result::	Not Done	
				ne	
			Not Done::	Not Done	
				ne	
			Lab Normal Range:	Not Done	
				ne	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.d Sponsor ID:

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.e

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			Test::	Not Done
				ne
			Result::	Not Done
				ne
			Not Done::	Not Done
				ne
			Lab Normal Range:	Not Done
				ne

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.e Sponsor ID:

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			Test::	Not Done	
				ne	
			Result::	Not Done	
				ne	
			Not Done::	Not Done	
				ne	
			Lab Normal Range:	Not Done	
				ne	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.f Sponsor ID:

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			Test::	Not Done
				ne
			Result::	Not Done
				ne
			Not Done::	Not Done
				ne
			Lab Normal Range:	Not Done
				ne

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.g Sponsor ID:

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Feb-03-2021 11:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Audit Trail

Form Version: 30-Jul-2020 21:28

Form Status:

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Lab Panel:

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HEMATOLOGY	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Holston Medical Group 105 West Stone Drive Kingsport, TN 37660	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/3/2021	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined I 1 identifier: Test:: Hemoglobin _PX1 Result:: 14.1 Not Done::	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			Lab Normal Range <i>Low</i> : 11.5 <i>High</i> 15.5 <i>Unit</i> g/dL	
--	--	--	--	--

5.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hemoglobin_PX1	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 14.1	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 11.5 <i>High</i> 15.5 <i>Unit</i> g/dL	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.b

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id 2 entifier: Test:: Hematocrit_ PX2 Result:: 42.5 Not Done:: Lab Normal Range <i>Low</i> : 34.5 <i>High</i> 46.5 <i>Unit</i> %	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History
on Feb/03/2021**Form Version:** 30-Jul-2020 21:28**Form Status:** Data Complete, Frozen**Site No:** 1167**Site Name:** (1167) Holston Medical Group**Subject No:** 11671009**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hematocrit_PX2	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 42.5	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 34.5 <i>High</i> 46.5 <i>Unit</i> %	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined I 3 dentifier: Test:: Erythrocytes _PX3	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			Result:: 4.81	
			Not Done::	
			Lab Normal Range <i>Low</i>	
			:	3.89
				<i>High</i>
				5.33
			<i>Unit</i>	
				10 ⁹ /L

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History
on Feb/03/2021**Form Version:** 30-Jul-2020 21:28**Form Status:** Data Complete, Frozen**Site No:** 1167**Site Name:** (1167) Holston Medical Group**Subject No:** 11671009**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Erythrocytes_PX3	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4.81	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 3.89 <i>High</i> 5.33 <i>Unit</i> 10 ⁹ /L	Initial Entry

5.d

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Platelets_P X5	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			Result:: 192	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			140	
			<i>High</i>	
			400	
			<i>Unit</i>	
			10 ¹² /L	

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.d Sponsor ID:

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 5	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Platelets_PX5	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 192	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <i>Low</i> 140 <i>High</i> 400 <i>Unit</i> 10 ¹² /L	Initial Entry

5.e

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Sponsor-Defined Id 7 entifier: Test:: Leukocytes_ PX7	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

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Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			Result:: 5.9	
			Not Done::	
			Lab Normal Range <i>Low</i>	
			:	3.0
				<i>High</i>
				10.0
				<i>Unit</i>
				10 ¹² /L

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.e Sponsor ID:

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 7	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Leukocytes_PX7	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 5.9	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <i>Low</i> 3.0 <i>High</i> 10.0 <i>Unit</i> 10 ¹² /L	Initial Entry

5.f

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Sponsor-Defined I 608 dentifier: Test:: Neutrophils_ PX608	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

			Result:: 73.0	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			e: 43.0	
			<i>High</i>	
			77.0	
			<i>Unit</i>	
			%	

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

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Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.f Sponsor ID:

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 608	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Neutrophils_PX608	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Feb-04-2021 12:57:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-04-2021 07:42:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Feb-04-2021 04:37:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7135337;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 73.0	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

(US & Canada)

5.f LNMT

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 43.0 <i>High</i> 77.0 <i>Unit</i> %	Initial Entry

5.g

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined I 609 dentifier: Test:: Eosinophils_ PX609 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.g Sponsor ID:

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 609	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Eosinophils_PX609	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT DONE	Initial Entry

5.h

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Sponsor-Defined I 612 dentifier: Test:: Monocytes_ PX612 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.h Sponsor ID:

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 612	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Monocytes_PX612	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

5.i

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id 610 entifier: Test:: Basophils_P X610 Result:: Not Done:: NOT DONE Lab Normal Range :	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

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Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.i Sponsor ID:

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 610	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Basophils_PX610	Initial Entry

5.i Not Done:

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT DONE	Initial Entry

5.j

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Sponsor-Defined 611 Identifier: Test:: Lymphocytes_ PX611 Result:: 19.40 Not Done:: Lab Normal Range: Low 18.0 High 40.0 Unit %	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.j Sponsor ID:

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 611	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Lymphocytes_PX611	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 19.40	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Feb-03-2021 11:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <i>Low</i> 18.0 <i>High</i> 40.0 <i>Unit</i> %	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail
on Feb/03/2021

Form Version: 30-Jul-2020 21:27

Form Status:

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Date	Location	User	Value	Reason
Feb-03-2021 11:52:01 (UTC-05:00) Eastern 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 Feb/03/2021

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

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1. Date:

Date	Location	User	Value	Reason
Feb-03-2021 11:52:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Feb/3/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Feb-03-2021 11:52:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Record Identifier:: 1 Systolic:: 126 Diastolic:: 88 Respiratory Rate in respirations/minute: Not D one Heart Rate in beats/minute: 76	Initial Entry
Feb-03-2021 11:52:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Record Identifier:: 1 Systolic:: 126 Diastolic:: 88 Respiratory Rate in respirations/minute: Heart Rate in beats/minute: 76	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Feb-03-2021 11:52:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Feb-03-2021 11:52:01	ACV0PFEINFP6000	(b) (6)	<u>Data Entry:</u>	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History on Feb/03/2021

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

(UTC-05:00) Eastern Time (US & Canada)		(b) (4)	126	
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2.a Diastolic:

Date	Location	User	Value	Reason
Feb-03-2021 11:52:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 88	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Feb-03-2021 11:52:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Feb-03-2021 11:52:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 76	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail on Feb/03/2021

Form Version: 30-Jul-2020 21:28

Form Status:

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Date	Location	User	Value	Reason
Feb-03-2021 11:52:44 (UTC-05:00) Eastern 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 Feb/03/2021 History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date:

Date	Location	User	Value	Reason
Feb-03-2021 11:52:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/3/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Feb-03-2021 11:52:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Oxygen Saturation: 98.0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Feb-03-2021 11:52:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Feb-03-2021 11:52:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 98.0	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History on Feb/03/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date Time of Assessment:

Date	Location	User	Value	Reason
Feb-03-2021 11:52:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Feb-03-2021 11:52:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Feb-03-2021 11:52:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Feb-03-2021 11:53:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Feb-03-2021 11:53:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Feb-03-2021 11:53:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Feb-03-2021 11:53:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Feb-03-2021 11:53:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/03/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

6. Ongoing?

Date	Location	User	Value	Reason
Feb-03-2021 11:53:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Audit Trail
on Feb/03/2021

Form Version: 06-Jul-2020 21:53

Form Status:

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Date	Location	User	Value	Reason
Feb-03-2021 11:53:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - eCRF Audit Trail History
on Feb/03/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date of Assessment:

Date	Location	User	Value	Reason
Feb-03-2021 11:53:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/3/2021	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Feb-03-2021 11:53:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHEST	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Feb-03-2021 11:53:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: X-RAY	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Feb-03-2021 11:53:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NORMAL	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Mar/08/2021

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: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-08-2021 09:39:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/8/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Mar-08-2021 09:39:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_A1	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled
Visit on Mar/08/2021**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1167**Site Name:** (1167) Holston Medical Group**Subject No:** 11671009**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Mar-08-2021 09:39:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-08-2021 09:39:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-08-2021 09:40:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-08-2021 09:39:41 (UTC-05:00) Eastern 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-08-2021 09:39:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/8/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-08-2021 09:40:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BR1DX7	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Mar/08/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.a Sample ID

Date	Location	User	Value	Reason
Mar-08-2021 09:40:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BR1DX7	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-08-2021 09:40:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BNVSrk	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-08-2021 09:40:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BNVSrk	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-08-2021 09:40:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BNVSRL	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-08-2021 09:40:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BNVSRL	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-07-2020 13:14:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/7/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-07-2020 13:14:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-07-2020 13:14:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Date	Location	User	Value	Reason
Aug-24-2020 14:51:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Date	Location	User	Value	Reason
Nov-16-2020 14:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

*** THIS REPEATING FORM HAS BEEN DELETED ***

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Date	Location	User	Value	Reason
Feb-08-2021 08:33:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	added to COVID illness page
Feb-01-2021 13:14:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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Date	Location	User	Value	Reason
Mar-08-2021 08:21:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Category:

Date	Location	User	Value	Reason
Aug-24-2020 14:51:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Aug-24-2020 14:51:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-16-2020 15:31:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Closed	Appreciate the prompt resolution. Thank you.
Nov-16-2020 14:51:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	separated terms
Nov-16-2020 11:48:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Reissued:Opened	The page has been unfrozen. If the term will be reported as Acute cholecystitis with cholelithiasis, please consider splitting the term as separate events to facilitate coding and match Safety database. Thank you.
Nov-16-2020 09:09:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	I can change the adverse event to cholelithiasis with acute cholectystitis but the page is

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

				frozen
Nov-15-2020 15:09:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Opened	Per FU report, the subject has "findings consistent with cholelithiasis and acute cholecystitis". Please revise and update AE log accordingly.
Oct-24-2020 00:16:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Appreciate the prompt response. Thank you.
Oct-23-2020 13:24:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	added
Oct-22-2020 13:32:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Opened	If test was performed = YES, please provide results in narrative. If test was NOT performed or NOT available, please add this information as well so it is reflected in the narrative.
Oct-21-2020 13:50:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	do I just put this in the narrative? I didn't see a specific place on the form for this.
Oct-21-2020 11:03:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form to provide whether COVID testing was performed (yes/no) and if yes, the

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

				results. Thank you
Aug-24-2020 14:51:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Acute Cholecystitis	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-02-2020 08:01:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	onset date updated in CRF. Issue resolved
Sep-01-2020 08:50:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Sep-01-2020 08:50:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/21/2020 UNK:UNK	Changed Information
Sep-01-2020 07:31:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2020328447
Aug-24-2020 14:51:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/22/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Aug-24-2020 14:51:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Aug/22/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Aug-24-2020 14:51:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1167) Holston Medical Group

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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Nov-02-2020 16:36:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 2: Closed	Response satisfies query
Nov-02-2020 08:32:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Nov-02-2020 08:32:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associat ed with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event requir e or prolong hospitalization? YES Did this serious event result in persistent or significant di sability/incapacity? NO Is this serious event life thre atening? NO	Changed Information

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Header Text: c4591001

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Site No: 1167

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			Other medically important serious event NO	
Oct-30-2020 15:55:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 2: Reissued:Opened	GPDClin: Thank you for the correction! Please clarify if "yes" to "medically important event" needs to be changed to be consistent with SAE report.
Oct-30-2020 10:25:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Oct-30-2020 10:25:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO	Transcription Error

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1167**Subject No:** 11671009**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1167) Holston Medical Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23

			Other medically important serious event	
			YES	
Oct-30-2020 08:21:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	GPDClin: Please clarify the SAE criterion. The SAE report indicated the criterion was hospitalization. If that's correct, please make correction here.
Oct-29-2020 19:04:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (b) (4)	Query 2: Candidate	GPDClin: Please clarify the SAE criterion. The SAE report indicated the criterion was hospitalization. If that's correct, please make correction here.
Aug-26-2020 04:29:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-24-2020 14:51:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Acute Cholecystitis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Aug-24-2020 14:51:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result	Initial Entry

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Generated By: (b) (4)

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			<p>in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>NO</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>YES</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
Aug-24-2020 14:51:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Aug-24-2020 14:51:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i>	Initial Entry

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Subject No: 11671009

Generated By: (b) (4)

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Subject Initials: ---

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			Cholelithiasis and sudden weight loss due to bariatric surgery 2018	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Aug-24-2020 14:51:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Aug-24-2020 14:51:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Aug-24-2020 14:51:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Aug-24-2020 14:51:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Aug-24-2020 14:51:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
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Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

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Aug-26-2020 04:29:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020328447	Initial Entry
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Header Text: c4591001

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Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Nov-16-2020 14:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-16-2020 14:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-16-2020 14:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Cholelithiasis	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-16-2020 14:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/21/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-16-2020 14:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Aug/22/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Nov-16-2020 14:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Nov-16-2020 14:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Nov-16-2020 14:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-20-2020 00:34:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-19-2020 09:44:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The bariatric surgery was 1 year before her entering the study and the PI feels she had cholelithiasis due to her weight loss

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Subject No: 11671009

Generated By: (b) (4)

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<p>Nov-19-2020 07:38:50 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000.InFormAdapter.Discrepancy</p>	<p>PFE SDQ PROD (b) (4)</p>	<p>Query 1: Opened</p>	<p>Please review "If not related to study treatment other" field, the following text was indicated in the comment field [bariatric surgery]. Any symptoms, AEs or other key data should be collected on the appropriate page. Please review and update as necessary. (b) (4)</p>
<p>Nov-16-2020 14:50:41 (UTC-05:00) Eastern Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p>Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Sudden weight loss</p>	<p>Initial Entry</p>

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				oss due to b ariat ric s urge ry
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-16-2020 14:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-16-2020 14:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-16-2020 14:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Nov-16-2020 14:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERED/RESOLVED WITH SEQUELAE	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-16-2020 14:50:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Feb-01-2021 13:14:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-01-2021 13:14:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-08-2021 16:02:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Feb-08-2021 08:33:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	added to COVID illness page
Feb-05-2021 16:29:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Closed	Response satisfies query
Feb-05-2021 16:28:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Reissued:Opened	Clin: Per Prot Section 8.3.7., COVID-19 related MYCOPLASMA PNEUMONIA does not qualify as AE and please should be documented only on the COVID-19 CRF ILLNESS DETAILS form as

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				MYCOPLASMA PNEUMONIA and should not be captured on the AE CRF page
Feb-05-2021 14:17:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	This has been captured as a COVID illness now
Feb-05-2021 14:17:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	we have reported this as a COVID illness visit now
Feb-05-2021 12:38:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Reissued:Opened	Clin: Please the data should still be captured on the appropriate CRF pages (as for any late data, we will still capture it and not ignore it) but a swab will not be required since the symptoms have resolved >4d
Feb-05-2021 12:37:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Reissued:Opened	Medical monitor: Despite telehealth visit was not done, please complete the potential COVID-19 Illness Visit CRF forms with all information available. Should be captured also on the SOD CRF form and a NASAL SWAB will not be collected
Feb-02-2021 11:33:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	she has no active symptoms
Feb-02-2021 11:32:51 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Subject did not report this illness and

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1167**Subject No:** 11671009**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Deleted**Site Name:** (1167) Holston Medical Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23***** THIS REPEATING FORM HAS BEEN DELETED *****

Time (US & Canada)				she has not active COVID 19 illness symptoms
Feb-02-2021 11:19:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Opened	Clin: Per Prot Sect 8.13., COVID-19 related PNEUMONIA, should trigger a potential COVID-19 Illness Visit irrespective of perceived etiology or clinical significance, captured only on the appropriate CRF forms and a NASAL SWAB COLLECTED ASAP
Feb-02-2021 11:17:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Per prot Sect 8.1, at any time, a participant develops acute respiratory illness (see Section 8.13), for the purposes of the study subject will be considered to potentially have COVID-19 illness
Feb-01-2021 13:14:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mycoplasma pneumonia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-01-2021 13:14:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/26/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

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Date	Location	User	Value	Reason
Feb-01-2021 13:14:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-01-2021 13:14:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-01-2021 13:14:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-01-2021 13:14:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-01-2021 13:14:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment(s), this event is due to:	Initial Entry

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			OTHER	
			<i>If Other, specify:</i>	
			Atypical bacteria	

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-01-2021 13:14:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-01-2021 13:14:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-01-2021 13:14:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Feb-01-2021 13:14:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERING/RESOLVING	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Feb-01-2021 13:14:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Category:

Date	Location	User	Value	Reason
Mar-08-2021 08:21:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-08-2021 08:21:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-08-2021 08:21:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Acute hepatitis	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-08-2021 08:21:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/25/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-08-2021 08:21:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-08-2021 08:21:53	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

(UTC-05:00) Eastern Time (US & Canada)

(b) (4)

2

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Mar-08-2021 15:28:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-08-2021 08:21:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Acute hepatitis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Mar-08-2021 08:21:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity?	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1167) Holston Medical Group

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Generated Time (GMT): 29-Mar-2021 12:23

			NO	
			Is this serious event life threatening?	
			NO	
			Other medically important serious event	
			NO	

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Mar-08-2021 08:21:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-12-2021 09:56:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This was reported as a AE but it was after visit 3 so not a reportable AE. I deleted this see AE page for this subject.
Mar-12-2021 08:43:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Opened	Thank you for the clarification. Since subject had pneumonia and it was associated to the SAE of hepatitis, pls revise the AE for an additional/separate AE. Thanks
Mar-11-2021 14:19:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	no she was admitted for the already reported acute hepatitis which they feel was caused by the antibiotics she

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1167**Subject No:** 11671009**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Answered Queries**Site Name:** (1167) Holston Medical Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23

				took when she had pneumonia which was 01Feb2021
Mar-11-2021 13:40:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued:Opened	Thank you for confirming. Since it is relevant for the current SAE, pls provide information about the infection/or additional diagnosis. Was the subject hospitalized for pneumonia? Thanks
Mar-11-2021 08:15:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Mycoplasma pneumonia
Mar-11-2021 07:31:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Medical Monitor. Pls advise the condition that was been treated with antibiotics, this information is missing in safety report. Thanks
Mar-08-2021 08:21:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> suspected due to doxycycline and Zithromax	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-08-2021 08:21:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Date	Location	User	Value	Reason
Mar-08-2021 08:21:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-08-2021 08:21:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Mar-08-2021 08:21:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERING/RESOLVING	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Mar-08-2021 08:21:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Mar-08-2021 15:28:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021241196	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Date	Location	User	Value	Reason
Oct-07-2020 13:14:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-07-2020 13:14:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-07-2020 13:14:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-07-2020 13:14:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Oct-07-2020 17:49:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Cl osed	Discrepancy has been closed.
Oct-07-2020 15:16:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: A nswered	New Information
Oct-07-2020 15:16:08	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry :	New Information

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

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Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

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(UTC-05:00) Eastern Time (US & Canada)			Fluzone (Influenza vaccine)	
Oct-07-2020 14:56:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify FLUZONE as follows...Multiple formulations available. Please clarify if reporting FLUZONE (FLUCONAZOLE) or FLUZONE (INFLUENZA VACCINE) or other and update the term. Thank you.
Oct-07-2020 13:14:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Fluzone	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Oct-07-2020 13:14:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/6/2020	Initial Entry

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Header Text: c4591001

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Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

Form Status:

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

*** THIS REPEATING FORM HAS BEEN DELETED ***

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Date	Location	User	Value	Reason
Feb-11-2021 08:56:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	not prohibited
Feb-03-2021 11:57:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF
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Form Status: Data Complete, Deleted, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

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
Feb-03-2021 11:57:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Feb-03-2021 11:57:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CORTICOSTEROIDS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Feb-03-2021 11:57:59 (UTC-05:00) Eastern 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-12-2021 19:04:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-11-2021 08:55:40 (UTC-05:00) Eastern Time (US &	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	will delete

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF
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Form Status: Data Complete, Deleted, Verified

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Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

*** THIS REPEATING FORM HAS BEEN DELETED ***

Canada)				
Feb-11-2021 02:10:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY: Dexamethasone sodium phosphate is reported on 03FEB2021. 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-10-2021 14:32:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Candidate	CLINQUERY: Dexamethasone sodium phosphate is reported on 03FEB2021. 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-03-2021 16:46:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Feb-03-2021 13:49:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error

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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: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

*** THIS REPEATING FORM HAS BEEN DELETED ***

Feb-03-2021 13:49:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entr Y: Dexameth asone sodi um phosph hate	Transcription Error
Feb-03-2021 13:45:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Clarify DESAMETHASONE SODIUM PHOSPHATE as follows...Should the spelling be DEXAMETHASONE SODIUM PHOSPHATE? If so, edit. Otherwise clarify or provide reference/label. Thank you.
Feb-03-2021 11:57:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entr Y: Desameth asone sodi um phosph hate	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Feb-03-2021 11:57:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Feb-03-2021 11:57:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: mL	Initial Entry

7. Dose Frequency:

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF
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Form Status: Data Complete, Deleted, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

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*** THIS REPEATING FORM HAS BEEN DELETED ***

Date	Location	User	Value	Reason
Feb-03-2021 11:57:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> ONCE	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Feb-03-2021 11:57:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Feb-03-2021 11:57:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Feb/3/2021	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Feb-03-2021 11:57:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date: Feb/3/2021	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (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: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date of Visit

Date	Location	User	Value	Reason
Dec-16-2020 13:27:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/15/2020	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Dec-16-2020 13:27:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-16-2020 13:27:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Dec-16-2020 13:27:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date of Visit

Date	Location	User	Value	Reason
Dec-16-2020 13:28:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/16/2020	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF
Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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I. Consent Was:

Date	Location	User	Value	Reason
Dec-16-2020 13:28:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Dec/16/2020	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION
- eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Dec-16-2020 13:29:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/16/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-16-2020 13:29:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-16-2020 13:29:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Lab Panel:

Date	Location	User	Value	Reason
Dec-16-2020 13:30:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Dec-16-2020 13:30:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Dec-16-2020 13:30:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Dec-16-2020 13:30:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Dec-16-2020 13:30:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Dec-16-2020 13:30:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Id Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Dec-16-2020 13:30:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Dec-16-2020 13:30:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Dec-16-2020 13:30:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Dec-16-2020 13:30:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (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: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Data Origin

Date	Location	User	Value	Reason
Dec-16-2020 13:30:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-16-2020 13:30:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-16-2020 13:30:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-16-2020 13:30:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-16-2020 13:30:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-16-2020 13:30:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM9BJ3	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (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: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.a Sample ID

Date	Location	User	Value	Reason
Dec-16-2020 13:30:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BM9BJ3	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-16-2020 13:31:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BSGHG5	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-16-2020 13:31:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BSGHG5	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-16-2020 13:31:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BSGHG6	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-16-2020 13:31:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BSGHG6	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (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: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Data Origin

Date	Location	User	Value	Reason
Dec-16-2020 13:31:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-16-2020 13:31:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-16-2020 13:31:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-16-2020 13:31:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-16-2020 13:31:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-16-2020 13:31:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM9BJ2	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (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: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.a Sample ID

Date	Location	User	Value	Reason
Dec-16-2020 13:31:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BM9BJ2	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Dec-16-2020 14:21:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Dec-16-2020 14:21:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Dec-16-2020 14:21:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Dec-16-2020 14:21:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/16/2020 13:38	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Dec-16-2020 14:21:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Dec-16-2020 14:21:16 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Time (US & Canada)				
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7. Route:

Date	Location	User	Value	Reason
Dec-16-2020 14:21:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Dec-16-2020 14:21:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Dec-16-2020 14:21:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Dec-16-2020 14:21:16 (UTC-05:00) Eastern 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
Dec-16-2020 14:21:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Dec-16-2020 13:27:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/15/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Dec-16-2020 13:27:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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I. Date of Visit

Date	Location	User	Value	Reason
Jan-27-2021 12:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Queried in error
Jan-27-2021 11:00:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per source, this visit occurred on 06/JAN/21. Please review and update DOV as necessary.
Jan-04-2021 12:00:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/4/2021	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Lab Panel:

Date	Location	User	Value	Reason
Jan-04-2021 12:01:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jan-04-2021 12:01:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-04-2021 12:01:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Jan-04-2021 12:01:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Jan-04-2021 12:01:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
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090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 10-Dec-2020 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Jan-04-2021 12:01:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Result:: Not Done::	Initial Entry
			Not Applicable Not Applicable Not Applicable Not Applicable	

6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-04-2021 12:01:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-04-2021 12:01:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jan-04-2021 12:01:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Jan-04-2021 12:01:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (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: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Data Origin

Date	Location	User	Value	Reason
Jan-04-2021 12:01:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-04-2021 12:01:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-04-2021 12:01:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-04-2021 12:01:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-04-2021 12:01:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/4/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-04-2021 12:01:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BM9BJV	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (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: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.a Sample ID

Date	Location	User	Value	Reason
Jan-04-2021 12:01:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BM9BJV	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-04-2021 13:34:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-04-2021 13:34:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-04-2021 13:34:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-04-2021 13:34:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/4/2021 13:33	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-04-2021 13:34:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-04-2021 13:34:05 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Time (US & Canada)

7. Route:

Date	Location	User	Value	Reason
Jan-04-2021 13:34:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-04-2021 13:34:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-04-2021 13:34:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-04-2021 13:34:05 (UTC-05:00) Eastern 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
Jan-04-2021 13:34:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-01-2021 13:11:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/1/2021	Initial Entry

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: CONTACT OUTCOME - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Contact Type:

Date	Location	User	Value	Reason
Feb-01-2021 13:12:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Feb-01-2021 13:12:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Contact: Feb/1/2021	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001**Visit:** FURTHER_VACCINATION_EOT -
Unscheduled**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete, Frozen, Verified**Site No:** 1167**Site Name:** (1167) Holston Medical Group**Subject No:** 11671009**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Feb-05-2021 09:29:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Both date is same
Feb-04-2021 16:00:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Ope ned	DMW7155316;Status on the Disposition - Treatment form is COMPLETED, but Date is different than Visit 3 Date. Please review and update as appropriate.
Feb-04-2021 07:48:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : Feb/1/ 2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-04-2021 07:48:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: OPEN LABEL TREATMENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-04-2021 07:48:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Subject Status

Date	Location	User	Value	Reason
Oct-07-2020 13:14:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-17-2020 15:47:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-17-2020 15:41:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Mar-08-2021 15:28:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-08-2021 08:22:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	added
Mar-08-2021 05:40:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2021241196 acute hepatitis(onset date: 25Feb2021)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Oct-07-2020 13:14:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/7/2020	Initial Entry
Aug-17-2020 15:47:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/17/2020	Initial Entry

090177e196ae308d\Final\Final On: 01-Apr-2021 04:09 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1167

Subject No: 11671009

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1167) Holston Medical Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Aug-17-2020 15:41:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Aug/17/2020	Initial Entry
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Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1167

Site Name: (1167) Holston Medical Group

Subject No: 11671009

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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I. Casebook Signature

Date	Location	User	Value	Reason
Oct-21-2020 10:46:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry