

**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:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Cohort Selection**

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

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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** MAIN INFORMED CONSENT

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/14/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[12351071]
2.	Birth Date:	(b) (6) 1970
3.	Sex:	MALE
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:** 1235

**Subject No:** 12351071

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

**Form:** DATE OF VISIT

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/14/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**Form Comments**

**Inclusion Criteria Not Met**

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

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

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

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation/Death	Sep/14/2020
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: 1235

Subject No: 12351071

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1235) LSU Health Shreveport

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 19:09

[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:	UNK/UNK/2010
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Asthma]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Dyslipidemia]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/14/2020
2.	Weight:	[240.0]
3.	Unit:	LB
4.	Height:	[71.0]
5.	Unit:	in
6.	Body Mass Index:	[33.5]

**Vital Signs Details**

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



**Header Text:** c4591001

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

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** RANDOMIZATION

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Sep/14/2020
2.	Randomization Number:	[88827]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/14/2020
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	[BLD3S3]
5.b	Sample ID	[BLD3S2]
5.c	Sample ID	[BP1D74]

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**Header Text:** c4591001

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

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

**Site No:** 1235

**Subject No:** 12351071

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

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

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/14/2020
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	[BP1D70]
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**Header Text:** c4591001

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

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** VACCINATION

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/14/2020 09:50
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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**Header Text:** c4591001

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

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

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

**Visit:** V2\_VAX2\_L

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 20-Feb-2021 02:16

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** VITAL SIGNS - TEMP

**Form Status:** Not Started

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1235

**Subject No:** 12351071

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

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

**Form Status:** Not Started

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** V2\_VAX2\_L

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** VACCINATION

**Form Status:** Not Started

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**Vaccination**

1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

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**Header Text:** c4591001

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

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** DATE OF VISIT

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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**Date of Visit**

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

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/24/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BSMPZ4]
5.b	Sample ID	[BP0YK3]
5.c	Sample ID	[BSMPZ2]

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET  
on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/22/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Sep/22/2020

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Signs and Symptoms**

1.	Date of Assessment:	Sep/22/2020
2.	Date of First Symptom Started:	Sep/21/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Sep/25/2020

**Symptoms**

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

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19  
on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

**Symptoms - Other**

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

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

**Form:** MICROBIOLOGY SPECIMEN

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Sep/22/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** MICROBIOLOGY SPECIMEN  
on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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**Microbiology Specimen**

1.	Actual Date of Collection:	Sep/22/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	POSITIVE
8.	Comments/Findings/Details:	[ ]
9.	Trade Name Other, Specify:	[LSU EVT Lab- PCR analysis- CLIA-certified lab]

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Sep/22/2020
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	[CV50417]
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090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**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:** HEALTH CARE UTILIZATION  
on Sep/22/2020**Form Version:** 15-Sep-2020 21:53**Form Status:** Data Complete, Frozen, Verified**Site No:** 1235**Site Name:** (1235) LSU Health Shreveport**Subject No:** 12351071**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09[eCRF Audit Trail History](#)**Health Care Utilization**

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

**Health Care Utilization Other**

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

3.	Has the subject been hospitalized due to potential COVID-19 illness?	YES Has the subject been in intensive care due to potential COVID-19 illness? YES
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**Header Text:** c4591001

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

**Form:** HOSPITALIZATION DETAILS

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1.	HOSPITALIZATION STATUS	ICU	Sep/22/2020	NO Discharge Date:  Sep/26/2020	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS  
on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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**Hospitalization Details**

Hospitalization Details		HOSPITALIZATION STATUS
1.	Hospitalization Category:	
2.	Hospitalization Term:	ICU
3.	Admission Date:	Sep/22/2020
4.	Ongoing?	NO Discharge Date: Sep/26/2020

**Header Text:** c4591001

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

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT  
on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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**Respiratory Treatment**

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

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS  
on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Illness Details**

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [COVID-19 ILLNESS]  Date of Diagnosis: Sep/22/2020
3.	Toxicity Grade:	2



**Header Text:** c4591001

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

**Form:** ILLNESS DETAILS - SEVERE

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE  
on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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**Illness Details**

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

Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

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

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 15-Sep-2020 21:51

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result	Form Instance																								
2.	CLINICAL CHEMISTRY	Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport, LA 71103	Sep/22/2020	BLOOD	<table border="1"> <thead> <tr> <th>Sponsor-Defined Identifier</th> <th>Test:</th> <th>Result:</th> </tr> </thead> <tbody> <tr> <td>329</td> <td>C Reactive Protein_PX329</td> <td>1.35</td> </tr> <tr> <td>30</td> <td>Alanine Aminotransferase_PX30</td> <td>97</td> </tr> <tr> <td>28</td> <td>Aspartate Aminotransferase_PX28</td> <td>44</td> </tr> <tr> <td>35</td> <td>Alkaline Phosphatase_PX35</td> <td>69</td> </tr> <tr> <td>21</td> <td>Bilirubin_PX21</td> <td>0.5</td> </tr> <tr> <td>47</td> <td>Blood Urea Nitrogen_PX47</td> <td>13</td> </tr> <tr> <td>48</td> <td>Creatinine_PX48</td> <td>1.0</td> </tr> </tbody> </table>	Sponsor-Defined Identifier	Test:	Result:	329	C Reactive Protein_PX329	1.35	30	Alanine Aminotransferase_PX30	97	28	Aspartate Aminotransferase_PX28	44	35	Alkaline Phosphatase_PX35	69	21	Bilirubin_PX21	0.5	47	Blood Urea Nitrogen_PX47	13	48	Creatinine_PX48	1.0	<a href="#">Repeating Pages</a>
					Sponsor-Defined Identifier	Test:	Result:																							
					329	C Reactive Protein_PX329	1.35																							
					30	Alanine Aminotransferase_PX30	97																							
					28	Aspartate Aminotransferase_PX28	44																							
					35	Alkaline Phosphatase_PX35	69																							
					21	Bilirubin_PX21	0.5																							
					47	Blood Urea Nitrogen_PX47	13																							
48	Creatinine_PX48	1.0																												
329	C Reactive Protein_PX329	1.35																												
30	Alanine Aminotransferase_PX30	97																												
28	Aspartate Aminotransferase_PX28	44																												
35	Alkaline Phosphatase_PX35	69																												
21	Bilirubin_PX21	0.5																												
47	Blood Urea Nitrogen_PX47	13																												
48	Creatinine_PX48	1.0																												
3.	CLINICAL CHEMISTRY	Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport, LA 71103	Sep/23/2020	BLOOD	<table border="1"> <thead> <tr> <th>Sponsor-Defined Identifier</th> <th>Test:</th> <th>Result:</th> </tr> </thead> <tbody> <tr> <td>329</td> <td>C Reactive Protein_PX329</td> <td>1.77</td> </tr> <tr> <td>30</td> <td>Alanine Aminotransferase_PX30</td> <td>94</td> </tr> <tr> <td>28</td> <td>Aspartate Aminotransferase_PX28</td> <td>50</td> </tr> <tr> <td>35</td> <td>Alkaline Phosphatase_PX35</td> <td>66</td> </tr> <tr> <td>21</td> <td>Bilirubin_PX21</td> <td>0.4</td> </tr> </tbody> </table>	Sponsor-Defined Identifier	Test:	Result:	329	C Reactive Protein_PX329	1.77	30	Alanine Aminotransferase_PX30	94	28	Aspartate Aminotransferase_PX28	50	35	Alkaline Phosphatase_PX35	66	21	Bilirubin_PX21	0.4	<a href="#">Repeating Pages</a>						
					Sponsor-Defined Identifier	Test:	Result:																							
					329	C Reactive Protein_PX329	1.77																							
					30	Alanine Aminotransferase_PX30	94																							
					28	Aspartate Aminotransferase_PX28	50																							
					35	Alkaline Phosphatase_PX35	66																							
21	Bilirubin_PX21	0.4																												
329	C Reactive Protein_PX329	1.77																												
30	Alanine Aminotransferase_PX30	94																												
28	Aspartate Aminotransferase_PX28	50																												
35	Alkaline Phosphatase_PX35	66																												
21	Bilirubin_PX21	0.4																												

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 15-Sep-2020 21:51

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result	Form Instance																								
					<table border="1"> <thead> <tr> <th>Sponsor-Defined Identifier</th> <th>Test:</th> <th>Result:</th> </tr> </thead> <tbody> <tr> <td>47</td> <td>Blood Urea Nitrogen_PX47</td> <td>12</td> </tr> <tr> <td>48</td> <td>Creatinine_PX48</td> <td>0.8</td> </tr> </tbody> </table>	Sponsor-Defined Identifier	Test:	Result:	47	Blood Urea Nitrogen_PX47	12	48	Creatinine_PX48	0.8																
Sponsor-Defined Identifier	Test:	Result:																												
47	Blood Urea Nitrogen_PX47	12																												
48	Creatinine_PX48	0.8																												
4.	CLINICAL CHEMISTRY	Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport, LA 71103	Sep/24/2020	BLOOD	<table border="1"> <thead> <tr> <th>Sponsor-Defined Identifier</th> <th>Test:</th> <th>Result:</th> </tr> </thead> <tbody> <tr> <td>329</td> <td>C Reactive Protein_PX329</td> <td>0.78</td> </tr> <tr> <td>30</td> <td>Alanine Aminotransferase_PX30</td> <td>78</td> </tr> <tr> <td>28</td> <td>Aspartate Aminotransferase_PX28</td> <td>40</td> </tr> <tr> <td>35</td> <td>Alkaline Phosphatase_PX35</td> <td>58</td> </tr> <tr> <td>21</td> <td>Bilirubin_PX21</td> <td>0.4</td> </tr> <tr> <td>47</td> <td>Blood Urea Nitrogen_PX47</td> <td>9</td> </tr> <tr> <td>48</td> <td>Creatinine_PX48</td> <td>0.77</td> </tr> </tbody> </table>	Sponsor-Defined Identifier	Test:	Result:	329	C Reactive Protein_PX329	0.78	30	Alanine Aminotransferase_PX30	78	28	Aspartate Aminotransferase_PX28	40	35	Alkaline Phosphatase_PX35	58	21	Bilirubin_PX21	0.4	47	Blood Urea Nitrogen_PX47	9	48	Creatinine_PX48	0.77	<a href="#">Repeating Pages</a>
Sponsor-Defined Identifier	Test:	Result:																												
329	C Reactive Protein_PX329	0.78																												
30	Alanine Aminotransferase_PX30	78																												
28	Aspartate Aminotransferase_PX28	40																												
35	Alkaline Phosphatase_PX35	58																												
21	Bilirubin_PX21	0.4																												
47	Blood Urea Nitrogen_PX47	9																												
48	Creatinine_PX48	0.77																												
5.	CLINICAL CHEMISTRY	Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport, LA 71103	Sep/25/2020	BLOOD	<table border="1"> <thead> <tr> <th>Sponsor-Defined Identifier</th> <th>Test:</th> <th>Result:</th> </tr> </thead> <tbody> <tr> <td>329</td> <td>C Reactive Protein_PX329</td> <td>[ ]</td> </tr> <tr> <td>30</td> <td>Alanine Aminotransferase_PX30</td> <td>81</td> </tr> </tbody> </table>	Sponsor-Defined Identifier	Test:	Result:	329	C Reactive Protein_PX329	[ ]	30	Alanine Aminotransferase_PX30	81	<a href="#">Repeating Pages</a>															
Sponsor-Defined Identifier	Test:	Result:																												
329	C Reactive Protein_PX329	[ ]																												
30	Alanine Aminotransferase_PX30	81																												

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 15-Sep-2020 21:51

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
					<b>Sponsor-Defined Identifier</b>	<b>Test:</b>	<b>Result:</b>	
					28	Aspartate Aminotransferase_PX28	39	
					35	Alkaline Phosphatase_PX35	62	
					21	Bilirubin_PX21	0.3	
					47	Blood Urea Nitrogen_PX47	12	
					48	Creatinine_PX48	0.73	
6.	CLINICAL CHEMISTRY	Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport, LA 71103	Sep/26/2020	BLOOD	<b>Sponsor-Defined Identifier</b>	<b>Test:</b>	<b>Result:</b>	<a href="#">Repeating Pages</a>
					329	C Reactive Protein_PX329		
					30	Alanine Aminotransferase_PX30	70	
					28	Aspartate Aminotransferase_PX28	28	
					35	Alkaline Phosphatase_PX35	60	
					21	Bilirubin_PX21	0.3	
					47	Blood Urea Nitrogen_PX47	12	
					48	Creatinine_PX48	0.80	

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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**Lab Chemistry Details**

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

**Lab Result**

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

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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

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

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Sep/22/2020

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

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**Site No:** 1235

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**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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

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**Header Text:** c4591001

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

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**Site Name:** (1235) LSU Health Shreveport

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**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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

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

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Sep/22/2020

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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**Lab Chemistry Details**

1.	Lab Panel:	CLINICAL CHEMISTRY
2.	Laboratory Name and Address	[Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport,LA 71103]
3.	Collection Date:	Sep/22/2020
4.	Specimen Type:	BLOOD

**Lab Result**

5.a	Sponsor ID:	[329]
	Test:	C Reactive Protein_PX329
	Result:	[1.35]
	Not Done:	
	LNMT	Low [0.00] High [0.90] Unit mg/dL

5.b	Sponsor ID:	[30]
	Test:	Alanine Aminotransferase_PX30
	Result:	[97]
	Not Done:	
	LNMT	Low [10] High [44] Unit U/L

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
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**Form Version:** 15-Sep-2020 21:51

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**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

5.c	Sponsor ID:	[28]
	Test:	Aspartate Aminotransferase_PX28
	Result:	[44]
	Not Done:	
	LNMT	Low [10] High [40] Unit U/L

5.d	Sponsor ID:	[35]
	Test:	Alkaline Phosphatase_PX35
	Result:	[69]
	Not Done:	
	LNMT	Low [55] High [135] Unit U/L

5.e	Sponsor ID:	[21]
	Test:	Bilirubin_PX21
	Result:	[0.5]
	Not Done:	
	LNMT	Low [0.1] High [1.0] Unit mg/dL

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

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

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5.f	Sponsor ID:	[47]
	Test:	Blood Urea Nitrogen_PX47
	Result:	[13]
	Not Done:	
	LNMT	Low [6] High [20] Unit mg/dL

5.g	Sponsor ID:	[48]
	Test:	Creatinine_PX48
	Result:	[1.0]
	Not Done:	
	LNMT	Low [0.5] High [1.40] Unit mg/dL

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Sep/22/2020

**Form Version:** 15-Sep-2020 21:51

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**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

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**Generated Time (GMT):** 29-Mar-2021 19:09

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[Form Audit Trail](#)

**Lab Chemistry Details**

1.	Lab Panel:	CLINICAL CHEMISTRY
2.	Laboratory Name and Address	[Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport,LA 71103]
3.	Collection Date:	Sep/23/2020
4.	Specimen Type:	BLOOD

**Lab Result**

5.a	Sponsor ID:	[329]
	Test:	C Reactive Protein_PX329
	Result:	[1.77]
	Not Done:	
	LNMT	Low [0.00] High [0.90] Unit mg/dL
5.b	Sponsor ID:	[30]
	Test:	Alanine Aminotransferase_PX30
	Result:	[94]
	Not Done:	
	LNMT	Low [10] High [44] Unit U/L

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
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**Subject No:** 12351071

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

**Generated Time (GMT):** 29-Mar-2021 19:09

5.c	Sponsor ID:	[28]
	Test:	Aspartate Aminotransferase_PX28
	Result:	[50]
	Not Done:	
	LNMT	Low [10] High [40] Unit U/L
5.d	Sponsor ID:	[35]
	Test:	Alkaline Phosphatase_PX35
	Result:	[66]
	Not Done:	
	LNMT	Low [55] High [135] Unit U/L
5.e	Sponsor ID:	[21]
	Test:	Bilirubin_PX21
	Result:	[0.4]
	Not Done:	
	LNMT	Low [0.1] High [1.0] Unit mg/dL

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Sep/22/2020

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

5.f	Sponsor ID:	[47]
	Test:	Blood Urea Nitrogen_PX47
	Result:	[12]
	Not Done:	
	LNMT	Low [6] High [20] Unit mg/dL

5.g	Sponsor ID:	[48]
	Test:	Creatinine_PX48
	Result:	[0.8]
	Not Done:	
	LNMT	Low [0.50] High [1.40] Unit mg/dL

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)



**Header Text:** c4591001

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**Lab Chemistry Details**

1.	Lab Panel:	CLINICAL CHEMISTRY
2.	Laboratory Name and Address	[Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport, LA 71103]
3.	Collection Date:	Sep/24/2020
4.	Specimen Type:	BLOOD

**Lab Result**

5.a	Sponsor ID:	[329]
	Test:	C Reactive Protein_PX329
	Result:	[0.78]
	Not Done:	
	LNMT	Low [0.00] High [0.90] Unit mg/L

5.b	Sponsor ID:	[30]
	Test:	Alanine Aminotransferase_PX30
	Result:	[78]
	Not Done:	
	LNMT	Low [10] High [44] Unit U/L

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

**Generated Time (GMT):** 29-Mar-2021 19:09

5.c	Sponsor ID:	[28]
	Test:	Aspartate Aminotransferase_PX28
	Result:	[40]
	Not Done:	
	LNMT	Low [10] High [40] Unit U/L
5.d	Sponsor ID:	[35]
	Test:	Alkaline Phosphatase_PX35
	Result:	[58]
	Not Done:	
	LNMT	Low [55] High [135] Unit U/L
5.e	Sponsor ID:	[21]
	Test:	Bilirubin_PX21
	Result:	[0.4]
	Not Done:	
	LNMT	Low [0.1] High [1.0] Unit mg/dL

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**Generated Time (GMT):** 29-Mar-2021 19:09

5.f	Sponsor ID:	[47]
	Test:	Blood Urea Nitrogen_PX47
	Result:	[9]
	Not Done:	
	LNMT	Low [6] High [20] Unit mg/dL

5.g	Sponsor ID:	[48]
	Test:	Creatinine_PX48
	Result:	[0.77]
	Not Done:	
	LNMT	Low [0.50] High [1.40] Unit mg/dL

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**Lab Chemistry Details**

1.	Lab Panel:	CLINICAL CHEMISTRY
2.	Laboratory Name and Address	[Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport, LA 71103]
3.	Collection Date:	Sep/25/2020
4.	Specimen Type:	BLOOD

**Lab Result**

5.a	Sponsor ID:	[329]
	Test:	C Reactive Protein_PX329
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit

5.b	Sponsor ID:	[30]
	Test:	Alanine Aminotransferase_PX30
	Result:	[81]
	Not Done:	
	LNMT	Low [10] High [44] Unit U/L

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

**Generated Time (GMT):** 29-Mar-2021 19:09

5.c	Sponsor ID:	[28]
	Test:	Aspartate Aminotransferase_PX28
	Result:	[39]
	Not Done:	
	LNMT	Low [10] High [40] Unit U/L
5.d	Sponsor ID:	[35]
	Test:	Alkaline Phosphatase_PX35
	Result:	[62]
	Not Done:	
	LNMT	Low [55] High [135] Unit U/L
5.e	Sponsor ID:	[21]
	Test:	Bilirubin_PX21
	Result:	[0.3]
	Not Done:	
	LNMT	Low [0.1] High [1.0] Unit mg/dL

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5.f	Sponsor ID:	[47]
	Test:	Blood Urea Nitrogen_PX47
	Result:	[12]
	Not Done:	
	LNMT	Low [6] High [20] Unit mg/dL

5.g	Sponsor ID:	[48]
	Test:	Creatinine_PX48
	Result:	[0.73]
	Not Done:	
	LNMT	Low [0.50] High [1.40] Unit mg/dL

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**Lab Chemistry Details**

1.	Lab Panel:	CLINICAL CHEMISTRY
2.	Laboratory Name and Address	[Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport, LA 71103]
3.	Collection Date:	Sep/26/2020
4.	Specimen Type:	BLOOD

**Lab Result**

5.a	Sponsor ID:	[329]
	Test:	C Reactive Protein_PX329
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [0.0] High [0.9] Unit mg/dL

5.b	Sponsor ID:	[30]
	Test:	Alanine Aminotransferase_PX30
	Result:	[70]
	Not Done:	
	LNMT	Low [10] High [44] Unit U/L

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**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

5.c	Sponsor ID:	[28]
	Test:	Aspartate Aminotransferase_PX28
	Result:	[28]
	Not Done:	
	LNMT	Low [10] High [40] Unit U/L
5.d	Sponsor ID:	[35]
	Test:	Alkaline Phosphatase_PX35
	Result:	[60]
	Not Done:	
	LNMT	Low [55] High [135] Unit U/L
5.e	Sponsor ID:	[21]
	Test:	Bilirubin_PX21
	Result:	[0.3]
	Not Done:	
	LNMT	Low [0.1] High [1.0] Unit mg/dL

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5.f	Sponsor ID:	[47]
	Test:	Blood Urea Nitrogen_PX47
	Result:	[12]
	Not Done:	
	LNMT	Low [6] High [20] Unit mg/dL

5.g	Sponsor ID:	[48]
	Test:	Creatinine_PX48
	Result:	[0.80]
	Not Done:	
	LNMT	Low [0.50] High [1.40] Unit mg/dL

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

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

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 15-Sep-2020 21:55

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date	Specimen Type	Lab Result	Form Instance																																	
2.	HEMATOLOGY	Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport, LA 71103	Sep/23/2020	BLOOD	<table border="1"> <thead> <tr> <th>Sponsor-Defined Identifier</th> <th>Test:</th> <th>Result:</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Hemoglobin_PX1</td> <td>13.8</td> </tr> <tr> <td>2</td> <td>Hematocrit_PX2</td> <td>40.5</td> </tr> <tr> <td>3</td> <td>Erythrocytes_PX3</td> <td>4.20</td> </tr> <tr> <td>5</td> <td>Platelets_PX5</td> <td>224</td> </tr> <tr> <td>7</td> <td>Leukocytes_PX7</td> <td>5.03</td> </tr> <tr> <td>608</td> <td>Neutrophils_PX608</td> <td>2.4</td> </tr> <tr> <td>609</td> <td>Eosinophils_PX609</td> <td>0.0</td> </tr> <tr> <td>612</td> <td>Monocytes_PX612</td> <td>1.1</td> </tr> <tr> <td>610</td> <td>Basophils_PX610</td> <td>0.03</td> </tr> <tr> <td>611</td> <td>Lymphocytes_PX611</td> <td>1.4</td> </tr> </tbody> </table>	Sponsor-Defined Identifier	Test:	Result:	1	Hemoglobin_PX1	13.8	2	Hematocrit_PX2	40.5	3	Erythrocytes_PX3	4.20	5	Platelets_PX5	224	7	Leukocytes_PX7	5.03	608	Neutrophils_PX608	2.4	609	Eosinophils_PX609	0.0	612	Monocytes_PX612	1.1	610	Basophils_PX610	0.03	611	Lymphocytes_PX611	1.4	<a href="#">Repeating Pages</a>
Sponsor-Defined Identifier	Test:	Result:																																					
1	Hemoglobin_PX1	13.8																																					
2	Hematocrit_PX2	40.5																																					
3	Erythrocytes_PX3	4.20																																					
5	Platelets_PX5	224																																					
7	Leukocytes_PX7	5.03																																					
608	Neutrophils_PX608	2.4																																					
609	Eosinophils_PX609	0.0																																					
612	Monocytes_PX612	1.1																																					
610	Basophils_PX610	0.03																																					
611	Lymphocytes_PX611	1.4																																					
3.	HEMATOLOGY	Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport, LA 71103	Sep/24/2020	BLOOD	<table border="1"> <thead> <tr> <th>Sponsor-Defined Identifier</th> <th>Test:</th> <th>Result:</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Hemoglobin_PX1</td> <td>13.1</td> </tr> <tr> <td>2</td> <td>Hematocrit_PX2</td> <td>39.1</td> </tr> <tr> <td>3</td> <td>Erythrocytes_PX3</td> <td>4.07</td> </tr> </tbody> </table>	Sponsor-Defined Identifier	Test:	Result:	1	Hemoglobin_PX1	13.1	2	Hematocrit_PX2	39.1	3	Erythrocytes_PX3	4.07	<a href="#">Repeating Pages</a>																					
Sponsor-Defined Identifier	Test:	Result:																																					
1	Hemoglobin_PX1	13.1																																					
2	Hematocrit_PX2	39.1																																					
3	Erythrocytes_PX3	4.07																																					

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 15-Sep-2020 21:55

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date	Specimen Type	Lab Result			Form Instance
					Sponsor-Defined Identifier	Test:	Result:	
					5	Platelets_PX5	199	
					7	Leukocytes_PX7	4.01	
					608	Neutrophils_PX608	1.4	
					609	Eosinophils_PX609	0.1	
					612	Monocytes_PX612	0.8	
					610	Basophils_PX610	0.02	
					611	Lymphocytes_PX611	1.7	
4.	HEMATOLOGY	Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport, LA 71103	Sep/25/ 2020	BLOOD	1	Hemoglobin_PX1	14.3	
					2	Hematocrit_PX2	42.2	
					3	Erythrocytes_PX3	4.40	
					5	Platelets_PX5	217	
					7	Leukocytes_PX7	4.11	
					608	Neutrophils_PX608	1.1	

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Generated Time (GMT): 29-Mar-2021 19:09

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date	Specimen Type	Lab Result			Form Instance
					Sponsor-Defined Identifier	Test:	Result:	
					609	Eosinophils_PX609	0.1	
					612	Monocytes_PX612	0.6	
					610	Basophils_PX610	0.02	
					611	Lymphocytes_PX611	2.3	
5.	HEMATOLOGY	Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport, LA 71103	Sep/26/ 2020	BLOOD	1	Hemoglobin_PX1	14.0	<a href="#">Repeating Pages</a>
					2	Hematocrit_PX2	41.1	
					3	Erythrocytes_PX3	4.33	
					5	Platelets_PX5	211	
					7	Leukocytes_PX7	4.42	
					608	Neutrophils_PX608	1.3	
					609	Eosinophils_PX609	0.1	
					612	Monocytes_PX612	0.6	
					610	Basophils_PX610	0.02	

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**Generated Time (GMT):** 29-Mar-2021 19:09

#	Category f or Lab Tes t	Vendor Name (DERIVED)	Collecti on Date :	Specim en Type	Lab Result			Form Insta nce
					Sponsor-Def ined Identifi er	Test:	Res ult:	
					611	Lymphocy tes_PX611	2.3	

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Form Status: Data Complete, Deleted, Frozen, Verified

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

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**Laboratory Data Hematology**

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

**Lab Result**

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

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

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

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

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

5.e	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	Leukoocytes_PX7	
	Result:	Not Done _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Done _____	<a href="#">Comments</a>
	LNMT	Not Done _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

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Subject No: 12351071

Subject Initials: ---

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

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

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology on Sep/22/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

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

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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**Laboratory Data Hematology**

1.	Lab Panel:	HEMATOLOGY
2.	Laboratory Name and Address	[Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport, LA 71103]
3.	Collection Date:	Sep/23/2020
4.	Specimen Type:	BLOOD

**Lab Result**

5.a	Sponsor ID:	[1]
	Test:	Hemoglobin_PX1
	Result:	[13.8]
	Not Done:	
	LNMT	Low [12.5] High [16.3] Unit g/dL

5.b	Sponsor ID:	[2]
	Test:	Hematocrit_PX2
	Result:	[40.5]
	Not Done:	
	LNMT	Low [36.7] High [47.1] Unit %

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

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5.c	Sponsor ID:	[3]
	Test:	Erythrocytes_PX3
	Result:	[4.20]
	Not Done:	
	LNMT	Low [4.6] High [6.2] Unit 10 <sup>12</sup> /L

5.d	Sponsor ID:	[5]
	Test:	Platelets_PX5
	Result:	[224]
	Not Done:	
	LNMT	Low [150] High [350] Unit 10 <sup>3</sup> /uL

5.e	Sponsor ID:	[7]
	Test:	Leukocytes_PX7
	Result:	[5.03]
	Not Done:	
	LNMT	Low [3.9] High [12.70] Unit 10 <sup>3</sup> /uL

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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

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5.f	Sponsor ID:	[608]
	Test:	Neutrophils_PX608
	Result:	[2.4]
	Not Done:	
	LNMT	Low [1.8] High [7.7] Unit 10 <sup>3</sup> /uL
5.g	Sponsor ID:	[609]
	Test:	Eosinophils_PX609
	Result:	[0.0]
	Not Done:	
	LNMT	Low [0.0] High [0.5] Unit 10 <sup>3</sup> /uL
5.h	Sponsor ID:	[612]
	Test:	Monocytes_PX612
	Result:	[1.1]
	Not Done:	
	LNMT	Low [0.3] High [1.0] Unit 10 <sup>3</sup> /uL

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

5.i	Sponsor ID:	[610]
	Test:	Basophils_PX610
	Result:	[0.03]
	Not Done:	
	LNMT	Low [0.0] High [0.20] Unit 10^3/uL

5.j	Sponsor ID:	[611]
	Test:	Lymphocytes_PX611
	Result:	[1.4]
	Not Done:	
	LNMT	Low [1.0] High [4.8] Unit 10^3/uL

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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**Laboratory Data Hematology**

1.	Lab Panel:	HEMATOLOGY
2.	Laboratory Name and Address	[Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport, LA 71103]
3.	Collection Date:	Sep/24/2020
4.	Specimen Type:	BLOOD

**Lab Result**

5.a	Sponsor ID:	[1]
	Test:	Hemoglobin_PX1
	Result:	[13.1]
	Not Done:	
	LNMT	Low [12.5] High [16.3] Unit g/dL
5.b	Sponsor ID:	[2]
	Test:	Hematocrit_PX2
	Result:	[39.1]
	Not Done:	
	LNMT	Low [36.7] High [47.1] Unit %

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**Header Text:** c4591001

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

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5.c	Sponsor ID:	[3]
	Test:	Erythrocytes_PX3
	Result:	[4.07]
	Not Done:	
	LNMT	Low [4.6] High [6.2] Unit 10 <sup>12</sup> /L

5.d	Sponsor ID:	[5]
	Test:	Platelets_PX5
	Result:	[199]
	Not Done:	
	LNMT	Low [150] High [350] Unit 10 <sup>3</sup> /uL

5.e	Sponsor ID:	[7]
	Test:	Leukocytes_PX7
	Result:	[4.01]
	Not Done:	
	LNMT	Low [3.9] High [12.7] Unit 10 <sup>3</sup> /uL

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

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5.f	Sponsor ID:	[608]
	Test:	Neutrophils_PX608
	Result:	[1.4]
	Not Done:	
	LNMT	Low [1.8] High [7.7] Unit 10 <sup>3</sup> /uL
5.g	Sponsor ID:	[609]
	Test:	Eosinophils_PX609
	Result:	[0.1]
	Not Done:	
	LNMT	Low [0.0] High [0.5] Unit 10 <sup>3</sup> /uL
5.h	Sponsor ID:	[612]
	Test:	Monocytes_PX612
	Result:	[0.8]
	Not Done:	
	LNMT	Low [0.3] High [1.0] Unit 10 <sup>3</sup> /uL

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

5.i	Sponsor ID:	[610]
	Test:	Basophils_PX610
	Result:	[0.02]
	Not Done:	
	LNMT	Low [0.0] High [0.2] Unit 10 <sup>3</sup> /uL

5.j	Sponsor ID:	[611]
	Test:	Lymphocytes_PX611
	Result:	[1.7]
	Not Done:	
	LNMT	Low [1.0] High [4.8] Unit 10 <sup>3</sup> /uL

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**Laboratory Data Hematology**

1.	Lab Panel:	HEMATOLOGY
2.	Laboratory Name and Address	[Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport, LA 71103]
3.	Collection Date:	Sep/25/2020
4.	Specimen Type:	BLOOD

**Lab Result**

5.a	Sponsor ID:	[1]
	Test:	Hemoglobin_PX1
	Result:	[14.3]
	Not Done:	
	LNMT	Low [12.5] High [16.3] Unit g/dL
5.b	Sponsor ID:	[2]
	Test:	Hematocrit_PX2
	Result:	[42.2]
	Not Done:	
	LNMT	Low [36.7] High [47.1] Unit %

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**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

5.c	Sponsor ID:	[3]
	Test:	Erythrocytes_PX3
	Result:	[4.40]
	Not Done:	
	LNMT	Low [4.6] High [6.2] Unit 10 <sup>12</sup> /L
5.d	Sponsor ID:	[5]
	Test:	Platelets_PX5
	Result:	[217]
	Not Done:	
	LNMT	Low [150] High [350] Unit 10 <sup>3</sup> /uL
5.e	Sponsor ID:	[7]
	Test:	Leukocytes_PX7
	Result:	[4.11]
	Not Done:	
	LNMT	Low [3.9] High [12.7] Unit 10 <sup>3</sup> /uL

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

5.f	Sponsor ID:	[608]
	Test:	Neutrophils_PX608
	Result:	[1.1]
	Not Done:	
	LNMT	Low [1.8] High [7.7] Unit 10 <sup>3</sup> /uL
5.g	Sponsor ID:	[609]
	Test:	Eosinophils_PX609
	Result:	[0.1]
	Not Done:	
	LNMT	Low [0.0] High [0.5] Unit 10 <sup>3</sup> /uL
5.h	Sponsor ID:	[612]
	Test:	Monocytes_PX612
	Result:	[0.6]
	Not Done:	
	LNMT	Low [0.3] High [1.0] Unit 10 <sup>3</sup> /uL

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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

5.i	Sponsor ID:	[610]
	Test:	Basophils_PX610
	Result:	[0.02]
	Not Done:	
	LNMT	Low [0.0] High [0.20] Unit 10^3/uL

5.j	Sponsor ID:	[611]
	Test:	Lymphocytes_PX611
	Result:	[2.3]
	Not Done:	
	LNMT	Low [1.0] High [4.8] Unit 10^3/uL

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**Laboratory Data Hematology**

1.	Lab Panel:	HEMATOLOGY
2.	Laboratory Name and Address	[Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport, LA 71103]
3.	Collection Date:	Sep/26/2020
4.	Specimen Type:	BLOOD

**Lab Result**

5.a	Sponsor ID:	[1]
	Test:	Hemoglobin_PX1
	Result:	[14.0]
	Not Done:	
	LNMT	Low [12.5] High [16.3] Unit g/dL

5.b	Sponsor ID:	[2]
	Test:	Hematocrit_PX2
	Result:	[41.1]
	Not Done:	
	LNMT	Low [36.7] High [47.1] Unit %

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
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**Form Version:** 15-Sep-2020 21:55

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

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**Subject Initials:** ---

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

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5.c	Sponsor ID:	[3]
	Test:	Erythrocytes_PX3
	Result:	[4.33]
	Not Done:	
	LNMT	Low [4.6] High [6.2] Unit 10 <sup>12</sup> /L
5.d	Sponsor ID:	[5]
	Test:	Platelets_PX5
	Result:	[211]
	Not Done:	
	LNMT	Low [150] High [350] Unit 10 <sup>3</sup> /uL
5.e	Sponsor ID:	[7]
	Test:	Leukocytes_PX7
	Result:	[4.42]
	Not Done:	
	LNMT	Low [3.9] High [12.7] Unit 10 <sup>3</sup> /uL

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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

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**Subject Initials:** ---

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

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5.f	Sponsor ID:	[608]
	Test:	Neutrophils_PX608
	Result:	[1.3]
	Not Done:	
	LNMT	Low [1.8] High [7.7] Unit 10 <sup>3</sup> /uL
5.g	Sponsor ID:	[609]
	Test:	Eosinophils_PX609
	Result:	[0.1]
	Not Done:	
	LNMT	Low [0.0] High [0.5] Unit 10 <sup>3</sup> /uL
5.h	Sponsor ID:	[612]
	Test:	Monocytes_PX612
	Result:	[0.6]
	Not Done:	
	LNMT	Low [0.3] High [1.0] Unit 10 <sup>3</sup> /uL

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**Site No:** 1235

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**Subject No:** 12351071

**Subject Initials:** ---

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

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5.i	Sponsor ID:	[610]
	Test:	Basophils_PX610
	Result:	[0.02]
	Not Done:	
	LNMT	Low [0.0] High [0.20] Unit 10^3/uL

5.j	Sponsor ID:	[611]
	Test:	Lymphocytes_PX611
	Result:	[2.3]
	Not Done:	
	LNMT	Low [1.0] High [4.8] Unit 10^3/uL

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**Header Text:** c4591001

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

**Form:** VITAL SIGNS - COVID

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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

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**Header Text:** c4591001

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

**Form:** VITAL SIGNS - COVID

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

#	Date:	Vital Signs Details			Form Instance
2.	Sep/26/2020	<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>
		1	118	79	
3.	Sep/25/2020	<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>
		1	182	72	
4.	Sep/24/2020	<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>
		1	120	80	
5.	Sep/23/2020	<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>
		1	145	94	
6.	Sep/22/2020	<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>
		1	131	95	

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** VITAL SIGNS - COVID  
on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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**Vital Signs**

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

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID  
on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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**Vital Signs**

1.	Date:	Sep/26/2020
----	-------	-------------

**Vital Signs Details**

2.a	Record Identifier:	1
	Systolic:	[118]
	Diastolic:	[79]
	Respiratory Rate in respirations/minute:	[16]
	Heart Rate in beats/minute:	[80]



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID  
on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

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**Vital Signs**

1.	Date:	Sep/25/2020
----	-------	-------------

**Vital Signs Details**

2.a	Record Identifier:	1
	Systolic:	[182]
	Diastolic:	[72]
	Respiratory Rate in respirations/minute:	[15]
	Heart Rate in beats/minute:	[90]

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID  
on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

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**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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**Vital Signs**

1.	Date:	Sep/24/2020
----	-------	-------------

**Vital Signs Details**

2.a	Record Identifier:	1
	Systolic:	[120]
	Diastolic:	[80]
	Respiratory Rate in respirations/minute:	[20]
	Heart Rate in beats/minute:	[83]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID  
on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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**Vital Signs**

1.	Date:	Sep/23/2020
----	-------	-------------

**Vital Signs Details**

2.a	Record Identifier:	1
	Systolic:	[145]
	Diastolic:	[94]
	Respiratory Rate in respirations/minute:	[11]
	Heart Rate in beats/minute:	[70]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** VITAL SIGNS - COVID  
on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

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**Vital Signs**

1.	Date:	Sep/22/2020
----	-------	-------------

**Vital Signs Details**

2.a	Record Identifier:	1
	Systolic:	[131]
	Diastolic:	[95]
	Respiratory Rate in respirations/minute:	[26]
	Heart Rate in beats/minute:	[111]

**Header Text:** c4591001

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

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

#	Date:	Vital Signs Details		Form Instance
1.	Sep/23/2020	<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>
		1	95.0	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 15-Sep-2020 21:54

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

#	Date:	Vital Signs Details		Form Instance
2. DELETED	Not Applicable	<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>
		1	Not Applicable	
3.	Sep/22/2020	<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>
		1	96.0	
4.	Sep/24/2020	<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>
		1	93.0	
5.	Sep/25/2020	<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>
		1	97.0	
6.	Sep/26/2020	<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>
		1	96.0	

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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**Vital Signs**

1.	Date:	Sep/23/2020
----	-------	-------------

**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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

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**Vital Signs**

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

**Vital Signs Details**

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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**Vital Signs**

1.	Date:	Sep/22/2020
----	-------	-------------

**Vital Signs Details**

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[96.0]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

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**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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**Vital Signs**

1.	Date:	Sep/24/2020
----	-------	-------------

**Vital Signs Details**

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[93.0]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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**Vital Signs**

1.	Date:	Sep/25/2020
----	-------	-------------

**Vital Signs Details**

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[97.0]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

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**Vital Signs**

1.	Date:	Sep/26/2020
----	-------	-------------

**Vital Signs Details**

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[96.0]

**Header Text:** c4591001

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

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS  
on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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**Oxygenation Parameters**

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

**Header Text:** c4591001

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

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS  
on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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**Concomitant Medications**

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

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**Header Text:** c4591001

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

**Form:** IMAGING

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Sep/22/2020	CHEST	X-RAY	ABNORMAL <i>If abnormal, specify findings:</i>  Minimal bibasilar infiltrates	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** IMAGING  
on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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**Imaging**

1.	Date of Assessment:	Sep/22/2020
2.	Location of Assessment:	CHEST
3.	Type of Imaging Exam:	X-RAY
4.	Assessment:	ABNORMAL If abnormal, specify findings: [Minimal bibasilar infiltrates]

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Oct/22/2020

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

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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**Date of Visit**

1.	Date of Visit	Oct/22/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Oct/22/2020

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/22/2020
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	[BLD43G]
5.b	Sample ID	[BLD43F]
5.c	Sample ID	[BP1DR4]

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**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:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

**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:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** DISPOSITION - TREATMENT

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Sep/22/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	NO LONGER MEETS ELIGIBILITY CRITERIA
4.	Specify Status:	[Exclusion Criteria 5]

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**Disposition - Follow-Up**

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



**Header Text:** c4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** Logs - Unscheduled

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Not Started

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**Adverse Event Report**

1.	Category:	
2.	AE ID:	[ ]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[ ]
4.	Start Date Time:	//
5.	Is the adverse event still ongoing?	
6.	Toxicity Grade:	
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).	
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.	
9.	Is this event related to study treatment:	
10.	Latest Action Taken with Study Treatment:	
11.	Was a Concomitant Medication given?	
12.	Was a Non-Drug Treatment given?	
13.	What was the outcome of this adverse event?:	

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Not Started

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

14.	Did the adverse event cause the subject to be discontinued from the study?	
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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**Medication Error**

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

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**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**Concomitant Medications**

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

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)



**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**Concomitant Medications**

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

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

**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:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

#	Transfusion Type	Date of Transfusion	Form Instance
1.			<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[Back to Form](#)

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:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VITAL SIGNS - TEMP

**Form Version:** 20-Feb-2021 02:16

**Form Status:** Not Started

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

**Vital Signs**

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

**Vital Signs Details**

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



**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

**Vaccination**

1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (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:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

**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:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** DATE OF VISIT

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Dec/16/2020
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:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** DATE OF VISIT

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Dec/18/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** INFORMED CONSENT - FURTHER VACCINATION

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Informed Consent - Further Vaccination**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Dec/18/2020
----	--------------	--

**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:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

**Form Comments**

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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



**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1235

**Subject No:** 12351071

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

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

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

1.	Date of Completion/Discontinuation/Death :	Dec/18/2020
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/18/2020
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	[BP0Y20]
5.b	Sample ID	[BRV43K]
5.c	Sample ID	[BRV43M]

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1235

**Subject No:** 12351071

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

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

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Dec/18/2020
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	[BP0Y1D]
-----	-----------	----------

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** VACCINATION

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Dec/18/2020 09:48
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

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** TREATMENT UNBLINDED

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Dec/16/2020
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** WITHDRAWAL OF CONSENT

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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

**Withdrawal Of Consent**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** DEATH DETAILS CODED

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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

**Death Details**

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

**Cause of Death**

2.	Cause of Death Status:	Not Applicable _____
	Cause of Death:	Not Applicable _____ [ ]

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** DATE OF VISIT

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Date of Visit**

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



**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1235

**Subject No:** 12351071

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

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

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/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	[BP0Y6B]
-----	-----------	----------

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** VACCINATION

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/8/2021 10:46
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

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** DATE OF VISIT

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/5/2021
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** CONTACT OUTCOME

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Contact Outcome**

1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Feb/5/2021
3.	Comments:	[ ]

**Header Text:** c4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V104\_MONTH6

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V105\_MONTH18

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

<b>Header Text:</b> c4591001	
<b>Visit:</b> V105_MONTH18	<b>Form:</b> CONTACT OUTCOME
<b>Form Version:</b> 22-Apr-2020 21:04	<b>Form Status:</b> Not Started
<b>Site No:</b> 1235	<b>Site Name:</b> (1235) LSU Health Shreveport
<b>Subject No:</b> 12351071	<b>Subject Initials:</b> ---
<b>Generated By:</b> (b) (4)	<b>Generated Time (GMT):</b> 29-Mar-2021 19:09

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:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Feb/5/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Sep/22/2020

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

[Audit Trail](#)

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
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**Header Text:** c4591001

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

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

**Site No:** 1235

**Subject No:** 12351071

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

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

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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Item	Date	User	Comment
Form	Sep-14-2020 09:12:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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Item	Date	User	Comment
Form	Oct-27-2020 12:47:14 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Sep/22/2020

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

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

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**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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Item	Date	User	Comment
1	Oct-27-2020 12:47:14 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
on Sep/22/2020

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

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

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**Subject No:** 12351071

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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Item	Date	User	Comment
2	Oct-27-2020 12:47:14 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
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Item	Date	User	Comment
3	Oct-27-2020 12:47:14 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
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Item	Date	User	Comment
4	Oct-27-2020 12:47:14 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
5	Oct-27-2020 12:47:14 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments  
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Item	Date	User	Comment
6	Oct-27-2020 12:47:14 (UTC-06:00) Central 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 Sep/22/2020

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

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

**Site No:** 1235

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**Subject No:** 12351071

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

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Item	Date	User	Comment
Form	Oct-27-2020 12:47:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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on Sep/22/2020

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

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Item	Date	User	Comment
1	Oct-27-2020 12:47:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments  
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Item	Date	User	Comment
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Item	Date	User	Comment
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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

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

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

**Site No:** 1235

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Item	Date	User	Comment
Form	Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Initial log line was inadvertently skipped. First Chemistry value available is documented on log line 2. <hr/> Not Done

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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
5.b	Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Initial log line was inadvertently skipped. First Chemistry value available is documented on log line 2. <hr/> Not Done

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Item	Date	User	Comment
5.c	Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Initial log line was inadvertently skipped. First Chemistry value available is documented on log line 2. <hr/> Not Done

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Item	Date	User	Comment
5.c	Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Initial log line was inadvertently skipped. First Chemistry value available is documented on log line 2. <hr/> Not Done



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Item	Date	User	Comment
5.d	Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Initial log line was inadvertently skipped. First Chemistry value available is documented on log line 2. <hr/> Not Done

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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Item	Date	User	Comment
5.e	Oct-27-2020 12:49:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

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5.j	Oct-27-2020 12:49:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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Item	Date	User	Comment
Form	Oct-13-2020 10:58:09 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments on Sep/22/2020

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

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**Site Name:** (1235) LSU Health Shreveport

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**Generated Time (GMT):** 29-Mar-2021 19:09

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Item	Date	User	Comment
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Item	Date	User	Comment
2.a	Oct-13-2020 10:58:09 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments  
on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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Item	Date	User	Comment
Form	Oct-27-2020 12:47:50 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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**Header Text:** c4591001

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on Sep/22/2020

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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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

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

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**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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**Subject No:** 12351071

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Item	Date	User	Comment
Form	Dec-18-2020 13:38:53 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT - Comments

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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Item	Date	User	Comment
Form	Dec-18-2020 13:35:04 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** Disposition

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** WITHDRAWAL OF CONSENT - Comments

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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Item	Date	User	Comment
1	Dec-18-2020 13:35:04 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** DEATH DETAILS CODED - Comments

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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Item	Date	User	Comment
Form	Dec-18-2020 13:35:42 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Disposition

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** DEATH DETAILS CODED - Comments

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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Item	Date	User	Comment
1	Dec-18-2020 13:35:42 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

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

**Form Status:** Data Complete, Verified

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Feb-05-2021 10:01:40 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated

**Affidavit:**

N/A

John Vanchiere	Approved	Jan-20-2021 17:40:29 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, JohnVanchiere, 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-18-2020 13:33:58 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

John Vanchiere	Approved	Dec-03-2020 00:11:41 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, JohnVanchiere, 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.

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

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

**Form Status:** Data Complete, Verified

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

(b) (6)	N/A	Nov-30-2020 15:14:07 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

John Vanchiere	Approved	Nov-24-2020 16:34:39 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Nov-24-2020 09:05:27 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

John Vanchiere	Approved	Nov-13-2020 22:31:02 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, JohnVanchiere, 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-12-2020 10:37:12 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

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

**Form Status:** Data Complete, Verified

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

John Vanchiere	Approved	Nov-02-2020 12:04:56 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, JohnVanchiere, 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 09:21:10 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

John Vanchiere	Approved	Oct-29-2020 13:59:11 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, JohnVanchiere, 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-27-2020 12:47:14 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

John Vanchiere	Approved	Oct-26-2020 10:06:36 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

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

**Form Status:** Data Complete, Verified

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

**Affidavit:**

By my dated signature below, I, JohnVanchiere, 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-22-2020 15:52:48 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

John Vanchiere	Approved	Oct-16-2020 16:17:25 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, JohnVanchiere, 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-16-2020 14:09:41 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

John Vanchiere	Approved	Oct-16-2020 11:05:06 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

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

**Form Status:** Data Complete, Verified

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

**Affidavit:**

By my dated signature below, I, JohnVanchiere, 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.

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** COHORT\_SELECTION - eCRF Audit Trail History

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Sep-14-2020 09:11:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-14-2020 09:11:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry



**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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*I. Consent Was:*

Date	Location	User	Value	Reason
Sep-14-2020 09:11:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Sep/14/2020	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1235

Subject No: 12351071

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1235) LSU Health Shreveport

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 19:09

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**1. Subject ID**

Date	Location	User	Value	Reason
Oct-08-2020 07:29:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Event invalidated in SDB. Issue resolved
Oct-07-2020 05:00:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	SAE RECON 1: Please submit a follow up AEM form to have the case invalidated in Pfizer Safety database.
Oct-06-2020 08:59:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	There was confusion on whether to report or not. The original answer was to report. After the SAE was reported, the answer was changed to not report the SAE. Instructions given by CRA and CTM.
Oct-06-2020 06:24:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020383652 SARS-CoV2 infection(onset date:22Sep2020)was reported as serious in Safety database.Per Clinical comment,'COVID19 hospitalisations ARE NOT reported as SAE.This is not a valid event for safety.' Please confirm
Sep-14-2020 09:11:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12351071	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
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090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: COHORT\_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

Sep-14-2020 09:11:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) 1970	Enrollment Entry
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**3. Sex:**

Date	Location	User	Value	Reason
Sep-14-2020 09:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Sep-14-2020 09:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-14-2020 09:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-14-2020 09:12:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/14/2020	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Sep-14-2020 09:40:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/14/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Sep-14-2020 09:40:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Sep-14-2020 09:40:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1235

Subject No: 12351071

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1235) LSU Health Shreveport

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 19:09

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*I.a*

Date	Location	User	Value	Reason
Sep-14-2020 09:41:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History Term:</b> Allergic Rhinitis <b>Start Date:</b> UNK/UNK/2010 <b>Ongoing:</b> YES	Initial Entry

*I.a Line/MH Number:*

Date	Location	User	Value	Reason
Sep-14-2020 09:41:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-14-2020 09:41:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Allergic Rhinitis	Initial Entry

*I.a Start Date:*

Date	Location	User	Value	Reason
Sep-14-2020 09:41:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2010	Initial Entry

*I.a Ongoing:*

Date	Location	User	Value	Reason
Sep-14-2020 09:41:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

*I.b*

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1235

Subject No: 12351071

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1235) LSU Health Shreveport

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 19:09

Date	Location	User	Value	Reason
Sep-14-2020 09:41:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number</b> 2 : <b>Medical History Term:</b> Asthma <b>Start Date:</b> UNK/UNK/2010 <b>Ongoing:</b> YES	Initial Entry

**1.b Line/MH Number:**

Date	Location	User	Value	Reason
Sep-14-2020 09:41:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-14-2020 09:41:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Asthma	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Sep-14-2020 09:41:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2010	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
Sep-14-2020 09:41:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.c**

Date	Location	User	Value	Reason
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090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1235

Subject No: 12351071

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1235) LSU Health Shreveport

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 19:09

Sep-14-2020 09:41:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 3 <b>Medical History Term:</b> Hypertension <b>Start Date:</b> UNK/UNK/2010 <b>Ongoing:</b> YES	Initial Entry
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**I.c Line/MH Number:**

Date	Location	User	Value	Reason
Sep-14-2020 09:41:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-14-2020 09:41:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hypertension	Initial Entry

**I.c Start Date:**

Date	Location	User	Value	Reason
Sep-14-2020 09:41:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2010	Initial Entry

**I.c Ongoing:**

Date	Location	User	Value	Reason
Sep-14-2020 09:41:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.d**

Date	Location	User	Value	Reason
Sep-14-2020 09:42:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number</b> 4 :	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1235

Subject No: 12351071

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1235) LSU Health Shreveport

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 19:09

			<b>Medical History Term:</b> <b>Start Date:</b> UNK/UNK/2015 <b>Ongoing:</b> YES	
--	--	--	--	--

**1.d Line/MH Number:**

Date	Location	User	Value	Reason
Sep-14-2020 09:42:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

**1.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Sep-14-2020 09:42:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dyslipidemia	Initial Entry

**1.d Start Date:**

Date	Location	User	Value	Reason
Sep-14-2020 09:42:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2015	Initial Entry

**1.d Ongoing:**

Date	Location	User	Value	Reason
Sep-14-2020 09:42:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1235

Subject No: 12351071

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1235) LSU Health Shreveport

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 19:09

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**1. Date:**

Date	Location	User	Value	Reason
Sep-14-2020 09:42:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/14/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Sep-14-2020 09:42:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 240.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Sep-14-2020 09:42:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Sep-14-2020 09:42:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 71.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Sep-14-2020 09:42:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> in	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Sep-14-2020 09:42:41 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 33.5	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1235

Subject No: 12351071

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1235) LSU Health Shreveport

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 19:09

Time (US & Canada)

7.a

Date	Location	User	Value	Reason
Sep-14-2020 09:42:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 36.5 <b>Temperature Unit:</b> C <b>Temperature Locat</b> ORAL CAVI <b>ion::</b> TY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-14-2020 09:42:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-14-2020 09:42:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.5	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-14-2020 09:42:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-14-2020 09:42:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** RANDOMIZATION - eCRF Audit Trail History

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Sep-14-2020 09:42:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/14/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Sep-14-2020 09:55:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 88827	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-14-2020 09:42:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-14-2020 09:42:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-14-2020 15:07:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-14-2020 09:42:55 (UTC-06:00) Central 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-14-2020 09:42:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/14/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-14-2020 15:07:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BLD3S3	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (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: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.a Sample ID

Date	Location	User	Value	Reason
Sep-14-2020 15:07:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BLD3S3	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-14-2020 15:07:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BLD3S2	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-14-2020 15:07:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BLD3S2	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-14-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP1D74	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-14-2020 15:07:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP1D74	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (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: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-14-2020 09:43:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-14-2020 09:43:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-14-2020 15:07:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-14-2020 09:43:02 (UTC-06:00) Central 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-14-2020 09:43:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/14/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-14-2020 15:07:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP1D70	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (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:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-14-2020 15:07:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP1D70	Initial Entry



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1235

Subject No: 12351071

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1235) LSU Health Shreveport

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 19:09

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-14-2020 09:56:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-14-2020 09:56:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-14-2020 09:56:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-14-2020 09:56:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/14/2020 09:50	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-14-2020 09:56:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Sep-14-2020 09:56:03 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1235

Subject No: 12351071

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1235) LSU Health Shreveport

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 19:09

Time (US & Canada)	(b) (4), (b) (6)
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**7. Route:**

Date	Location	User	Value	Reason
Sep-14-2020 09:56:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-14-2020 09:56:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OB SERVATION 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-14-2020 09:56:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Sep-14-2020 09:56:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICITY E-DIA RY NOT COLLECTED FOR THI S SUBJECT	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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*1. Date of Visit*

Date	Location	User	Value	Reason
Nov-24-2020 09:05:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/24/2020	Initial Entry

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Nov-24-2020 09:05:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-24-2020 09:05:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-24-2020 13:26:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-24-2020 09:05:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-24-2020 09:05:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/24/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-24-2020 13:26:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BSMPZ4	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.a Sample ID

Date	Location	User	Value	Reason
Nov-24-2020 13:26:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BSMPZ4	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-24-2020 13:26:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPOYK3	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-24-2020 13:26:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPOYK3	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-24-2020 13:26:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BSMPZ2	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-24-2020 13:26:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BSMPZ2	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Sep/22/2020**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1235**Site Name:** (1235) LSU Health Shreveport**Subject No:** 12351071**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09[Back to Form](#)**1. Date of Visit**

Date	Location	User	Value	Reason
Sep-22-2020 16:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Sep-22-2020 15:48:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-22-2020 13:48:05 (UTC-06:00) Central 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.
Sep-22-2020 13:48:05 (UTC-06:00) Central 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.
Sep-22-2020 13:48:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/22/2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 13:48:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Sep-22-2020 16:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/22/2020	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Sep-22-2020 16:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/21/2020	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Oct-07-2020 11:43:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-06-2020 13:18:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New information reported by subject.
Oct-06-2020 13:18:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Symptom Resolved : Sep/25/2020	New information reported by subject.
Oct-06-2020 12:03:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please confirm if symptoms are still ongoing?
Sep-22-2020 16:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.a**

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

Date	Location	User	Value	Reason
Sep-22-2020 16:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b> YES	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Sep-22-2020 16:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Sep-22-2020 16:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.b

Date	Location	User	Value	Reason
Sep-22-2020 16:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED COUGH <b>Symptom Present:</b> YES	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Sep-22-2020 16:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Sep-22-2020 16:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

4.c

Date	Location	User	Value	Reason
Oct-05-2020 09:36:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom:</b> NEW OR INCREASE D SHORTNESS OF B REATH <b>Symptom Present:</b> YES	New Information
Sep-22-2020 16:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom:</b> NEW OR INCREASE D SHORTNESS OF B REATH <b>Symptom Present:</b> NO	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

4.c Symptoms:

Date	Location	User	Value	Reason
Sep-22-2020 16:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Oct-05-2020 10:10:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-05-2020 09:36:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-05-2020 09:36:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	New Information
Oct-02-2020 23:37:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per source, patient was noted with increased SOB with min exertion seen at the Critical Care. Please confirm if answer should be "YES" accordingly
Sep-22-2020 16:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Sep-22-2020 16:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS <b>Symptom Present:</b> YES	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

4.d Symptoms:

Date	Location	User	Value	Reason
Sep-22-2020 16:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Sep-22-2020 16:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

4.e

Date	Location	User	Value	Reason
Sep-22-2020 16:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom NEW OR INCREASED MUSCLE PAIN Symptom YES Present:	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Sep-22-2020 16:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Sep-22-2020 16:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

4.f

Date	Location	User	Value	Reason
Sep-22-2020 16:05:20	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

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(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	<b>Symptoms</b> NEW LOSS OF TASTE OR SMELL <b>Symptom Present:</b> NO
--	--	------------------	--

4.f Symptoms:

Date	Location	User	Value	Reason
Sep-22-2020 16:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Sep-22-2020 16:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Sep-22-2020 16:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SORE THROAT <b>Symptom Present:</b> YES	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Sep-22-2020 16:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Sep-22-2020 16:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

4.h

Date	Location	User	Value	Reason
Sep-22-2020 16:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> DIARRHEA <b>Symptom Present:</b> NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Sep-22-2020 16:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Sep-22-2020 16:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Sep-22-2020 16:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITING <b>Symptom Present:</b> NO	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Sep-22-2020 16:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Sep-22-2020 16:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail  
on Sep/22/2020

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

**Form Status:**

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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Date	Location	User	Value	Reason
Sep-29-2020 11:10:43 (UTC-06:00) Central 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 Sep/22/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

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**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Sep-29-2020 11:10:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/22/2020	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Sep-29-2020 11:10:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWABBED MATERIAL	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Sep-29-2020 11:10:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NASOPHARYNX	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Sep-29-2020 11:10:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Sep-29-2020 11:10:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Oct-01-2020 02:00:34 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Sep/22/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

Time (US & Canada)				
Sep-30-2020 14:23:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Sep-30-2020 14:23:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	New Information
Sep-30-2020 09:34:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Trade name" is missing. Kindly review and update.

7. Test Result:

Date	Location	User	Value	Reason
Oct-12-2020 21:29:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Closed	Response satisfies query
Oct-12-2020 15:19:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	EOT form is complete.
Oct-08-2020 21:06:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Reissued:Opened	CLIQUEY: thank you for your response. please keep this query open till EOT form is completed.
Oct-08-2020 14:46:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SUBJECT IS NTO SCHEDULED FOR VACCINE 2. WILL ADD EOT FORM.
Oct-08-2020 13:37:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Opened	CLIQUEY: Given that the subject is symptomatic and has positive COVID test result, prior to vaccination. Please review as to whether the subject meets exclusion criteria? In

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History  
on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

				this case VAX#2 should not be done and EOT should be completed.
Sep-29-2020 11:10:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> POSITIVE	Initial Entry

**9. Trade Name Other, Specify:**

Date	Location	User	Value	Reason
Oct-05-2020 10:43:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-05-2020 08:23:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	per query
Oct-05-2020 08:23:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LSU EVT Lab- PCR analysis- C LIA-certified lab	per query
Oct-03-2020 07:54:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM Thanks for the response. However, kindly update the text 'CLIA-certified lab' in the required field as appropriate.
Oct-01-2020 09:31:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Testing was performed by PCR assay. The assay has been validated. The FDA's independent review of this validation is pending.
Oct-01-2020 07:47:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM : Please indicate whether the test was conducted in a CLIA- certified laboratory by including the text 'CLIA-certified lab'

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Sep/22/2020

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

				in the required field.
Sep-29-2020 11:10:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LSU EVT Lab- PCR analysis	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Sep/22/2020**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF -  
eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1235**Site Name:** (1235) LSU Health Shreveport**Subject No:** 12351071**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-22-2020 15:48:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-22-2020 15:48:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-22-2020 16:15:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-22-2020 15:48:46 (UTC-06:00) Central 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-22-2020 15:48:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/22/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-22-2020 16:15:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: CV50417	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-22-2020 16:15:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CV50417	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

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1. Data Origin

Date	Location	User	Value	Reason
Sep-22-2020 15:49:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-22-2020 15:49:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-22-2020 16:14:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Sep-22-2020 16:13:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: 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.
Sep-22-2020 16:13:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Sep-22-2020 16:13:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Transcription Error
Sep-22-2020 15:50:14	ACV0PFEINFP6000	auto query	Query 2: Candidate	'Sample Collected?'

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1235**Subject No:** 12351071**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1235) LSU Health Shreveport**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 19:09

(UTC-06:00) Central Time (US & Canada)		(autoquery)		is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-22-2020 15:50:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-22-2020 15:50:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/22/2020	Transcription Error
Sep-22-2020 15:49:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: 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.
Sep-22-2020 15:49:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Sep-22-2020 16:17:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-22-2020 16:17:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> nasal self swab was collected	Transcription Error
Sep-22-2020 16:14:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Entered text has either a carriage return (line break) or extra spaces at the

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

				end of the text or between words. Please correct by removing all data in the field and re-enter without adding extra spaces or using enter or tab keys.
Sep-22-2020 16:14:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> nasal self swab was collected	Initial Entry



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Sep/22/2020**Form Version:** 15-Sep-2020 21:53**Form Status:** Data Complete, Frozen, Verified**Site No:** 1235**Site Name:** (1235) LSU Health Shreveport**Subject No:** 12351071**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09[Back to Form](#)**1.a**

Date	Location	User	Value	Reason
Sep-22-2020 16:17:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIALIST <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry
Sep-22-2020 15:51:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIALIST <b>Occurrence of Visits or Contacts:</b>	Initial Entry

**1.a Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Sep-22-2020 15:51:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SPECIALIST	Initial Entry

**1.a Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Sep-22-2020 16:17:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**1.b**

Date	Location	User	Value	Reason
Sep-22-2020 16:17:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENCY ROOM <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry
Sep-22-2020 15:51:52 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Sep/22/2020

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

Time (US & Canada)			Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts:
--------------------	--	--	---

***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Sep-22-2020 15:51:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

***1.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Sep-22-2020 16:17:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

***1.c***

Date	Location	User	Value	Reason
Sep-22-2020 16:17:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry
Sep-22-2020 15:51:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts:	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Sep/22/2020

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

***1.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Sep-22-2020 15:51:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

***1.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Sep-22-2020 16:17:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.d***

Date	Location	User	Value	Reason
Sep-22-2020 16:17:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner</b> URGENT : CARE <b>Occurrence of Visits</b> NO <b>or Contacts:</b>	Initial Entry
Sep-22-2020 15:51:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner</b> URGENT : CARE <b>Occurrence of Visits</b> <b>or Contacts:</b>	Initial Entry

***1.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Sep-22-2020 15:51:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> URGENT CARE	Initial Entry

***1.d Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Sep-22-2020 16:17:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Sep/22/2020

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

*I.e*

Date	Location	User	Value	Reason
Sep-22-2020 15:51:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE CONSULTATION <b>Occurrence of Visits or Contacts:</b> YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

*I.e Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Sep-22-2020 15:51:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> TELEPHONE CONSULTATION	Initial Entry

*I.e Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Sep-22-2020 15:51:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

*I.f*

Date	Location	User	Value	Reason
Sep-22-2020 16:17:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTH ER <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry
Sep-22-2020 15:51:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTH ER <b>Occurrence of Visits or Contacts:</b>	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Sep/22/2020

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

**1.f Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Sep-22-2020 15:51:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

**1.f Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Sep-22-2020 16:17:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Has the subject been hospitalized due to potential COVID-19 illness?**

Date	Location	User	Value	Reason
Oct-07-2020 09:11:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-06-2020 09:15:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Oct-06-2020 09:15:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Has the subject been in intensive care due to potential COVID-19 illness?  YES	Changed Information
Oct-06-2020 06:55:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: The response is reported as 'Yes' however the response for "Has the Participant been in intensive care due to potential COVID-19 illness?" is missing. Kindly review and update.
Oct-05-2020 10:08:47	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)		query
Oct-05-2020 08:45:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-05-2020 08:45:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	New Information
Oct-03-2020 00:12:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please confirm entry and consider changing to be "YES" as subject was hospitalized on 22Sep2020
Sep-22-2020 15:51:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - Audit Trail  
on Sep/22/2020

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

**Form Status:**

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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Date	Location	User	Value	Reason
Oct-05-2020 09:02:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History on Sep/22/2020

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

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**1. Hospitalization Category:**

Date	Location	User	Value	Reason
Oct-05-2020 09:02:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> HOSPITALIZATION STATUS	Initial Entry

**2. Hospitalization Term:**

Date	Location	User	Value	Reason
Oct-20-2020 12:17:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Closed	CLIQUEY: Given that the subject has been hospitalized, please enter a separate line item to complete hospitalization details within this CRF as a separate line entry.
Oct-20-2020 09:39:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Query is ambiguous
Oct-20-2020 01:00:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLIQUEY: Given that the subject has been hospitalized, please complete hospitalization details within this CRF as a separate line entry.
Oct-19-2020 23:47:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rupal N Shah (b) (4)	Query 1: Candidate	CLIQUEY: Given that the subject has been hospitalized, please complete hospitalization details within this CRF as a separate line entry.
Oct-05-2020 09:02:39	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - eCRF Audit Trail History on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

(UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	ICU	
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**3. Admission Date:**

Date	Location	User	Value	Reason
Nov-09-2020 13:10:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-09-2020 12:58:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	all information is entered in multiple sections of the illness visit
Nov-09-2020 03:46:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLIQUEY: Hospitalization: This subject had COVID-19 Illness and was hospitalized. Please enter any available information (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...). Please make every effort to obtain these information.
Nov-06-2020 13:05:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	CLIQUEY: Hospitalization: This subject had COVID-19 Illness and was hospitalized. Please enter any available information (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...). Please make every effort to obtain these information.

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - eCRF Audit Trail History  
on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

Oct-05-2020 09:02:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/22/2020	Initial Entry
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**4. Ongoing?**

Date	Location	User	Value	Reason
Oct-05-2020 09:02:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Discharge Date:  Sep/26/2020	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: RESPIRATORY TREATMENT - eCRF Audit Trail History on Sep/22/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

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**1. What is the treatment Identifier?**

Date	Location	User	Value	Reason
Oct-27-2020 12:47:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Concomitant Non-drug Treatment Pre-specified:**

Date	Location	User	Value	Reason
Oct-27-2020 12:47:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Treatment:**

Date	Location	User	Value	Reason
Oct-27-2020 12:47:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Treatment:**

Date	Location	User	Value	Reason
Oct-27-2020 12:47:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Oct-27-2020 12:47:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Ongoing?**

Date	Location	User	Value	Reason
Oct-27-2020 12:47:14	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

(UTC-06:00) Central  
Time (US & Canada)

(b) (4), (b)  
(6)

Not Applicable

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - eCRF Audit Trail History on Sep/22/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Sep-29-2020 11:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID-19 ILLNESS	Initial Entry

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

Date	Location	User	Value	Reason
Oct-16-2020 10:33:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Oct-12-2020 15:40:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 3: Closed	Discrepancy has been closed.
Oct-12-2020 14:04:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Changed Information
Oct-12-2020 14:04:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnosis:</i>  COVID-19 ILLNESS  Date of Diagnosis:  Sep/22/2020	Changed Information

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - eCRF Audit Trail History on Sep/22/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

Oct-12-2020 13:08:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 3: Open ed	Clarify COVID ILLNESS as follows...The term appears incomplete. Are you reporting COVID-19 ILLNESS? If so, edit the term as such. Otherwise, clarify and edit the term as appropriate. Thank you.
Oct-12-2020 11:08:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Delet ed	Changed Information
Oct-12-2020 11:08:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-12-2020 11:08:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnosis:</i>  COVID illness  Date of Diagnosis:  Sep/22/2020	Changed Information
Oct-12-2020 01:15:08 (UTC-06:00) Central Time	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Reissued: Opened	Clin: Thank you. The form will be unfreeze. Please

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History  
on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

(US & Canada)				update the CTRF
Oct-12-2020 01:14:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Candidate	Clin: please unfreeze the CRF form to allow updating the form
Oct-08-2020 16:23:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please unlock and I will update.
Oct-08-2020 15:43:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Please since the local SARS-COV-2 test result is positive, please update the diagnosis as "COVID-19 illness".
Sep-29-2020 11:49:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnosis:</i>  Upper Respiratory Infection  Date of Diagnosis:  Sep/22/2020	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Sep-29-2020 11:49:33 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History  
on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

Time (US & Canada)				
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Oct-27-2020 12:47:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Subcategory of Clinical Event:**

Date	Location	User	Value	Reason
Oct-27-2020 12:47:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Was a diagnosis obtained?**

Date	Location	User	Value	Reason
Oct-27-2020 12:47:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Toxicity Grade:**

Date	Location	User	Value	Reason
Oct-27-2020 12:47:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

[Back to Form](#)

**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done <b>Test::</b> Not Done <b>Result::</b> Not Done	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

			Not Done::	Not Done
			Lab Normal Range:	Not Done

5.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.b

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done <b>Test::</b> Not Done <b>Result::</b> Not Done <b>Not Done::</b> Not Done <b>Lab Normal Range:</b> Not Done	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.b Sponsor ID:

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Test::</b>	Not Done	
			<b>Result::</b>	Not Done	
			<b>Not Done::</b>	Not Done	
			<b>Lab Normal Range:</b>	Not Done	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.c Sponsor ID:

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Test::</b>	Not Done	
			<b>Result::</b>	Not Done	
			<b>Not Done::</b>	Not Done	
			<b>Lab Normal Range:</b>	Not Done	



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.d Sponsor ID:

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Test::</b>	Not Done	
			<b>Result::</b>	Not Done	
			<b>Not Done::</b>	Not Done	
			<b>Lab Normal Range:</b>	Not Done	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.e Sponsor ID:

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.f

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Test::</b>	Not Done	
			<b>Result::</b>	Not Done	
			<b>Not Done::</b>	Not Done	
			<b>Lab Normal Range:</b>	Not Done	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Site No: 1235

Site Name: (1235) LSU Health Shreveport

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.f Sponsor ID:

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.g

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Test::</b>	Not Done	
			<b>Result::</b>	Not Done	
			<b>Not Done::</b>	Not Done	
			<b>Lab Normal Range:</b>	Not Done	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

**5.g Sponsor ID:**

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.g Test:**

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.g Result:**

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.g Not Done:**

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.g LNMT**

Date	Location	User	Value	Reason
Sep-30-2020 14:35:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Sep/22/2020

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:**

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:**

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Sep/22/2020

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:**

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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Date	Location	User	Value	Reason
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:**

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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Date	Location	User	Value	Reason
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:**

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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Date	Location	User	Value	Reason
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> CLINICAL CHEMISTRY	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Oct-16-2020 10:51:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-16-2020 09:14:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	complete
Oct-15-2020 22:12:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 1: Reissued:Opened	Apologies, can you please update the lab name for all your entries on this page. Please do not copy and paste or use carriage returns in lab name entries as this causes a technical issue for us.
Oct-15-2020 13:18:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	done
Oct-15-2020 13:18:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport,LA 71103	done
Oct-15-2020 13:11:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	There is a invalid character (Carriage returns) found in the lab name and address field.

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

				Please re-enter the lab name and address with out adding spaces before and after term and without pressing enter key. Please do update for all labs in the CRF.
Sep-29-2020 09:41:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport, LA 71103	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/22/2020	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLOOD	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Define</b> 329 <b>d Identifier:</b> <b>Test::</b> C Reactive Prot ein_PX329 <b>Result::</b> 1.35 <b>Not Done::</b>	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

			<b>Lab Normal Range:</b> <i>Low</i> 0.00  <i>High</i> 0.90  <i>Unit</i> mg/dL	
--	--	--	---	--

5.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 329	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C Reactive Protein_PX329	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1.35	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0.00  <i>High</i> 0.90  <i>Unit</i> mg/dL	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

**5.b**

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 30 <b>Test::</b> Alanine Aminotransferase_PX30 <b>Result::</b> 97 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 10 <i>High</i> 44 <i>Unit</i> U/L	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.b Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Alanine Aminotransferase_PX30	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 97	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 10  <i>High</i> 44  <i>Unit</i> U/L	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Aspartate Aminotransferase_PX28	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Result::</b> 44	
			<b>Not Done::</b>	
			<b>Lab Normal R</b> <i>Low</i>	
			<b>ange:</b> 10	
			<i>High</i>	
			40	
			<i>Unit</i>	
			U/L	

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:51**Form Status:** Data Complete, Frozen, Verified**Site No:** 1235**Site Name:** (1235) LSU Health Shreveport**Subject No:** 12351071**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 28	Initial Entry

**5.c Test:**

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aspartate Aminotransferase_PX2 8	Initial Entry

**5.c Result:**

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 44	Initial Entry

**5.c LNMT**

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 10  <i>High</i> 40  <i>Unit</i> U/L	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Define</b> 35 <b>d Identifier:</b> <b>Test::</b> Alkaline Phosph atase_PX35	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Result::</b> 69	
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b> <i>Low</i>	
			55	
			<i>High</i>	
			135	
			<i>Unit</i>	
			U/L	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.d Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 35	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Alkaline Phosphatase_PX35	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 69	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 55  <i>High</i> 135  <i>Unit</i> U/L	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Bilirubin_P X21	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Result::</b> 0.5	
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b> <i>Low</i>	
			0.1	
			<i>High</i>	
			1.0	
			<i>Unit</i>	
			mg/dL	

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:51**Form Status:** Data Complete, Frozen, Verified**Site No:** 1235**Site Name:** (1235) LSU Health Shreveport**Subject No:** 12351071**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 21	Initial Entry

**5.e Test:**

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Bilirubin_PX21	Initial Entry

**5.e Result:**

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0.5	Initial Entry

**5.e LNMT**

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 0.1  <i>High</i> 1.0  <i>Unit</i> mg/dL	Initial Entry

**5.f**

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Define</b> 47 <b>d Identifier:</b> <b>Test::</b> Blood Urea Nitr ogen_PX47	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Result::</b> 13	
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b> <i>Low</i>	
			6	
			<i>High</i>	
			20	
			<i>Unit</i>	
			mg/dL	



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.f Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 47	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Blood Urea Nitrogen_PX47	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 13	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 6  <i>High</i> 20  <i>Unit</i> mg/dL	Initial Entry

5.g

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Id</b> 48 <b>entifier:</b> <b>Test::</b> Creatinine_P X48	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Result::</b> 1.0	
			<b>Not Done::</b>	
			<b>Lab Normal Range</b> <i>Low</i>	
			:	0.5
				<i>High</i>
				1.40
			<i>Unit</i>	
			mg/dL	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.g Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 48	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Creatinine_PX48	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1.0	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Sep-29-2020 09:40:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>  <i>Low</i> 0.5  <i>High</i> 1.40  <i>Unit</i> mg/dL	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> CLINICAL CHEMISTRY	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Oct-16-2020 09:07:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ochsner LSU Health Shreveport 1 501 Kings Hwy Shreveport, LA 71 103	query response
Sep-29-2020 09:46:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport, LA 71103	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/23/2020	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLOOD	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 329	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

			<b>Test::</b> C Reactive Protein_PX329 <b>Result::</b> 1.77 <b>Not Done::</b> <b>Lab Normal Range:</b> Low 0.00 High 0.90 Unit mg/dL	
--	--	--	---	--

5.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 329	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C Reactive Protein_PX329	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1.77	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Low 0.00 High	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			0.90	
			<i>Unit</i> mg/dL	

**5.b**

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 30 <b>Test::</b> Alanine Aminotransferase_PX30 <b>Result::</b> 94 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 10  <i>High</i> 44  <i>Unit</i> U/L	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:51**Form Status:** Data Complete, Frozen, Verified**Site No:** 1235**Site Name:** (1235) LSU Health Shreveport**Subject No:** 12351071**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30	Initial Entry

**5.b Test:**

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Alanine Aminotransferase_PX30	Initial Entry

**5.b Result:**

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 94	Initial Entry

**5.b LNMT**

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 10  <i>High</i> 44  <i>Unit</i> U/L	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defin</b> 28 <b>ed Identifier:</b> <b>Test::</b> Aspartate Aminotr ansferase_PX28	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Result::</b> 50	
			<b>Not Done::</b>	
			<b>Lab Normal R</b> <i>Low</i>	
			<b>ange:</b> 10	
			<i>High</i>	
			40	
			<i>Unit</i>	
			U/L	



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.c Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 28	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aspartate Aminotransferase_PX2 8	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 50	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 10  <i>High</i> 40  <i>Unit</i> U/L	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Define</b> 35 <b>d Identifier:</b> <b>Test::</b> Alkaline Phosph atase_PX35	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Result::</b> 66	
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b> <i>Low</i>	
			55	
			<i>High</i>	
			135	
			<i>Unit</i>	
			U/L	

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:51**Form Status:** Data Complete, Frozen, Verified**Site No:** 1235**Site Name:** (1235) LSU Health Shreveport**Subject No:** 12351071**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 35	Initial Entry

**5.d Test:**

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Alkaline Phosphatase_PX35	Initial Entry

**5.d Result:**

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 66	Initial Entry

**5.d LNMT**

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 55  <i>High</i> 135  <i>Unit</i> U/L	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Bilirubin_P X21	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Result::</b> 0.4	
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b> <i>Low</i>	
			0.1	
			<i>High</i>	
			1.0	
			<i>Unit</i>	
			mg/dL	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.e Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 21	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Bilirubin_PX21	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0.4	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 0.1  <i>High</i> 1.0  <i>Unit</i> mg/dL	Initial Entry

5.f

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Define</b> 47 <b>d Identifier:</b> <b>Test::</b> Blood Urea Nitrogen_PX47	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Result::</b> 12	
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b> <i>Low</i>	
			6	
			<i>High</i>	
			20	
			<i>Unit</i>	
			mg/dL	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.f Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 47	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Blood Urea Nitrogen_PX47	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 12	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 6  <i>High</i> 20  <i>Unit</i> mg/dL	Initial Entry

5.g

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Id</b> 48 <b>entifier:</b> <b>Test::</b> Creatinine_P X48	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Result::</b> 0.8	
			<b>Not Done::</b>	
			<b>Lab Normal Range</b> <i>Low</i>	
			:	0.50
				<i>High</i>
				1.40
			<i>Unit</i>	
			mg/dL	



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.g Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 48	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Creatinine_PX48	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0.8	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Sep-29-2020 09:45:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 0.50  <i>High</i> 1.40  <i>Unit</i> mg/dL	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
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**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> CLINICAL CHEMISTRY	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Oct-16-2020 16:06:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 1: Closed	Response satisfies query
Oct-16-2020 15:49:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport, L A 71103	query
Oct-16-2020 14:09:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	done
Oct-16-2020 14:09:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport, LA 71103	done
Oct-16-2020 13:16:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	There is a invalid character (Carriage returns) found in the lab name and address field. Please re-enter the lab name and address with out adding spaces before and after term and without pressing enter key.
Oct-16-2020 09:08:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ochsner LSU Health Shreveport 1501 Kings Hwy	query response

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Header Text: c4591001

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Site No: 1235

Site Name: (1235) LSU Health Shreveport

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

			Shreveport,LA 71103	
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport, LA 71103	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/24/2020	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLOOD	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Define</b> 329 <b>d Identifier:</b> <b>Test::</b> C Reactive Prot ein_PX329 <b>Result::</b> 0.78 <b>Not Done::</b> <b>Lab Normal Range:</b> Low 0.00  High 0.90  Unit mg/L	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
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090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 329	Initial Entry
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5.a Test:

Date	Location	User	Value	Reason
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C Reactive Protein_PX329	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0.78	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 0.00  <i>High</i> 0.90  <i>Unit</i> mg/L	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 30 <b>Test::</b> Alanine Aminotransferase_PX30 <b>Result::</b> 78 <b>Not Done::</b>	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

			<b>Lab Normal Range:</b> <i>Low</i> 10  <i>High</i> 44  <i>Unit</i> U/L	
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5.b Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Alanine Aminotransferase_PX30	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 78	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 10  <i>High</i> 44  <i>Unit</i> U/L	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

5.c

Date	Location	User	Value	Reason
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Aspartate Aminotransferase_PX28 <b>Result::</b> 40 <b>Not Done:</b> <b>Lab Normal Range:</b> <i>Low</i> 10 <i>High</i> 40 <i>Unit</i> U/L	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:51**Form Status:** Data Complete, Frozen, Verified**Site No:** 1235**Site Name:** (1235) LSU Health Shreveport**Subject No:** 12351071**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 28	Initial Entry

**5.c Test:**

Date	Location	User	Value	Reason
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aspartate Aminotransferase_PX2 8	Initial Entry

**5.c Result:**

Date	Location	User	Value	Reason
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 40	Initial Entry

**5.c LNMT**

Date	Location	User	Value	Reason
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 10  <i>High</i> 40  <i>Unit</i> U/L	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Nov-02-2020 09:21:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 35 <b>Test::</b> Alkaline Phosphatase_PX35	Transcription Error

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Result::</b> 58 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 55 <i>High</i> 135 <i>Unit</i> U/L	
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 35 <b>Test::</b> Alkaline Phosphatase_PX35 <b>Result::</b> 58 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 55 <i>High</i> 135 <i>Unit</i> g/L	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.d Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 35	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Alkaline Phosphatase_PX35	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Nov-03-2020 21:37:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Nov-02-2020 09:21:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	updated
Oct-30-2020 12:09:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Please the Unit should be << U/L >> and update as appropriate
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 58	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Nov-02-2020 09:21:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Low 55  High 135	Transcription Error

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<i>Unit</i> U/L	
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 55  <i>High</i> 135  <i>Unit</i> g/L	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Bilirubin_P X21 <b>Result::</b> 0.4 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0.1  <i>High</i> 1.0  <i>Unit</i> mg/dL	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:51**Form Status:** Data Complete, Frozen, Verified**Site No:** 1235**Site Name:** (1235) LSU Health Shreveport**Subject No:** 12351071**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 21	Initial Entry

**5.e Test:**

Date	Location	User	Value	Reason
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Bilirubin_PX21	Initial Entry

**5.e Result:**

Date	Location	User	Value	Reason
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0.4	Initial Entry

**5.e LNMT**

Date	Location	User	Value	Reason
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 0.1  <i>High</i> 1.0  <i>Unit</i> mg/dL	Initial Entry

**5.f**

Date	Location	User	Value	Reason
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Define</b> 47 <b>d Identifier:</b> <b>Test::</b> Blood Urea Nitr ogen_PX47	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Result::</b> 9	
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b> <i>Low</i>	
			6	
			<i>High</i>	
			20	
			<i>Unit</i>	
			mg/dL	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.f Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 47	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Blood Urea Nitrogen_PX47	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 9	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 6  <i>High</i> 20  <i>Unit</i> mg/dL	Initial Entry

5.g

Date	Location	User	Value	Reason
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Id</b> 48 <b>entifier:</b> <b>Test::</b> Creatinine_P X48	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Result::</b> 0.77	
			<b>Not Done::</b>	
			<b>Lab Normal Range</b> <i>Low</i>	
			:	0.50
				<i>High</i>
				1.40
			<i>Unit</i>	
			mg/dL	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.g Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 48	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Creatinine_PX48	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 0.77	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Sep-29-2020 09:49:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <i>Low</i> 0.50  <i>High</i> 1.40  <i>Unit</i> mg/dL	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> CLINICAL CHEMISTRY	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Oct-16-2020 16:10:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 1: Closed	Response satisfies query
Oct-16-2020 15:52:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport, L A 71103	response to query
Oct-16-2020 14:10:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	done
Oct-16-2020 14:10:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport, LA 71103	done
Oct-16-2020 13:16:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	There is a invalid character (Carriage returns) found in the lab name and address field. Please re-enter the lab name and address with out adding spaces before and after term and without pressing enter key.
Oct-16-2020 09:09:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ochsner LSU Health Shreveport 1501 Kings Hwy	query response

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

			Shreveport,LA 71103	
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport, LA 71103	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-29-2020 09:56:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/25/2020	Transcription Error
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/24/2020	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLOOD	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-29-2020 09:56:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 329 <b>Test::</b> C Reactive Protein_PX329 <b>Result::</b> <b>Not Done::</b> NOT DONE <b>Lab Normal Range:</b>	Initial Entry
Sep-29-2020 09:54:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> C Reactive Protein_PX329	Transcription Error

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

			<b>Result:</b> <b>Not Done:</b> <b>Lab Normal Range:</b>	
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test:</b> C Reactive Protein_PX329 <b>Result:</b> <b>Not Done:</b> NOT DONE <b>Lab Normal Range:</b>	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 09:56:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 329	Initial Entry
Sep-29-2020 09:54:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 329	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C Reactive Protein_PX329	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Sep-29-2020 09:56:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

Sep-29-2020 09:54:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 30 <b>Test::</b> Alanine Aminotransferase_PX30 <b>Result::</b> 81 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 10 <i>High</i> 44 <i>Unit</i> U/L	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:51**Form Status:** Data Complete, Frozen, Verified**Site No:** 1235**Site Name:** (1235) LSU Health Shreveport**Subject No:** 12351071**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30	Initial Entry

**5.b Test:**

Date	Location	User	Value	Reason
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Alanine Aminotransferase_PX30	Initial Entry

**5.b Result:**

Date	Location	User	Value	Reason
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 81	Initial Entry

**5.b LNMT**

Date	Location	User	Value	Reason
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 10  <i>High</i> 44  <i>Unit</i> U/L	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Aspartate Aminotransferase_PX28	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Result::</b> 39	
			<b>Not Done::</b>	
			<b>Lab Normal R</b> <i>Low</i>	
			<b>ange:</b> 10	
			<i>High</i>	
			40	
			<i>Unit</i>	
			U/L	

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:51**Form Status:** Data Complete, Frozen, Verified**Site No:** 1235**Site Name:** (1235) LSU Health Shreveport**Subject No:** 12351071**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 28	Initial Entry

**5.c Test:**

Date	Location	User	Value	Reason
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aspartate Aminotransferase_PX2 8	Initial Entry

**5.c Result:**

Date	Location	User	Value	Reason
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 39	Initial Entry

**5.c LNMT**

Date	Location	User	Value	Reason
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 10  <i>High</i> 40  <i>Unit</i> U/L	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Define</b> 35 <b>d Identifier:</b> <b>Test::</b> Alkaline Phosph atase_PX35	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Result::</b> 62	
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b> <i>Low</i>	
			55	
			<i>High</i>	
			135	
			<i>Unit</i>	
			U/L	

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:51**Form Status:** Data Complete, Frozen, Verified**Site No:** 1235**Site Name:** (1235) LSU Health Shreveport**Subject No:** 12351071**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 35	Initial Entry

**5.d Test:**

Date	Location	User	Value	Reason
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Alkaline Phosphatase_PX35	Initial Entry

**5.d Result:**

Date	Location	User	Value	Reason
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 62	Initial Entry

**5.d LNMT**

Date	Location	User	Value	Reason
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 55  <i>High</i> 135  <i>Unit</i> U/L	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Bilirubin_P X21	Initial Entry



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Result::</b> 0.3	
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b> <i>Low</i>	
			0.1	
			<i>High</i>	
			1.0	
			<i>Unit</i>	
			mg/dL	

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:51**Form Status:** Data Complete, Frozen, Verified**Site No:** 1235**Site Name:** (1235) LSU Health Shreveport**Subject No:** 12351071**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 21	Initial Entry

**5.e Test:**

Date	Location	User	Value	Reason
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Bilirubin_PX21	Initial Entry

**5.e Result:**

Date	Location	User	Value	Reason
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0.3	Initial Entry

**5.e LNMT**

Date	Location	User	Value	Reason
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 0.1  <i>High</i> 1.0  <i>Unit</i> mg/dL	Initial Entry

**5.f**

Date	Location	User	Value	Reason
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Define</b> 47 <b>d Identifier:</b> <b>Test::</b> Blood Urea Nitr ogen_PX47	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Result::</b> 12	
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b> <i>Low</i>	
			6	
			<i>High</i>	
			20	
			<i>Unit</i>	
			mg/dL	

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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:51**Form Status:** Data Complete, Frozen, Verified**Site No:** 1235**Site Name:** (1235) LSU Health Shreveport**Subject No:** 12351071**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09**5.f Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 47	Initial Entry

**5.f Test:**

Date	Location	User	Value	Reason
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Blood Urea Nitrogen_PX47	Initial Entry

**5.f Result:**

Date	Location	User	Value	Reason
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 12	Initial Entry

**5.f LNMT**

Date	Location	User	Value	Reason
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 6  <i>High</i> 20  <i>Unit</i> mg/dL	Initial Entry

**5.g**

Date	Location	User	Value	Reason
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Id</b> 48 <b>entifier:</b> <b>Test::</b> Creatinine_P X48	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Result::</b> 0.73	
			<b>Not Done::</b>	
			<b>Lab Normal Range</b> <i>Low</i>	
			:	0.50
				<i>High</i>
				1.40
			<i>Unit</i>	
			mg/dL	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.g Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 48	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Creatinine_PX48	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0.73	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Sep-29-2020 09:53:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 0.50  <i>High</i> 1.40  <i>Unit</i> mg/dL	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

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**Subject Initials:** ---

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> CLINICAL CHEMISTRY	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Oct-16-2020 16:10:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 1: Closed	Response satisfies query
Oct-16-2020 15:55:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport, L A 71103	query
Oct-16-2020 14:11:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	done
Oct-16-2020 14:11:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport, LA 71103	done
Oct-16-2020 13:17:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	There is a invalid character (Carriage returns) found in the lab name and address field. Please re-enter the lab name and address with out adding spaces before and after term and without pressing enter key.
Oct-16-2020 09:09:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ochsner LSU Health Shreveport 1501 Kings Hwy	query response

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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020**Form Version:** 15-Sep-2020 21:51**Site No:** 1235**Subject No:** 12351071**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1235) LSU Health Shreveport**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 19:09

			Shreveport,LA 71103	
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport. LA 71103	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Oct-05-2020 10:09:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-05-2020 08:48:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-05-2020 08:48:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/26/2020	Changed Information
Oct-03-2020 00:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Lab chem results were entered twice for labs done on 24Sep20 . However Lab results for 26Sep20 were not entered, please update EDC accordingly.
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/24/2020	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLOOD	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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Site Name: (1235) LSU Health Shreveport

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Subject Initials: ---

Generated By: (b) (4)

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<p>Oct-05-2020 08:52:52 (UTC-06:00) Central Time (US &amp; Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>auto calc (autocalc)</p>	<p><b>Data Entry:</b>  <b>Sponsor-Defined Identifier:</b>  <b>Test::</b> C Reactive Protein_PX329  <b>Result::</b>  <b>Not Done::</b> NOT DONE  <b>Lab Normal Range:</b> <i>Low</i>  0.0    <i>High</i>  0.9    <i>Unit</i>  mg/dL</p>	<p>Initial Entry</p>
<p>Oct-05-2020 08:49:17 (UTC-06:00) Central Time (US &amp; Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>auto calc (autocalc)</p>	<p><b>Data Entry:</b>  <b>Sponsor-Defined Identifier:</b>  <b>Test::</b> C Reactive Protein_PX329  <b>Result::</b>  <b>Not Done::</b>  <b>Lab Normal Range:</b> <i>Low</i>  0.0    <i>High</i>  0.9    <i>Unit</i>  mg/dL</p>	<p>Transcription Error</p>
<p>Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US &amp; Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>auto calc (autocalc)</p>	<p><b>Data Entry:</b>  <b>Sponsor-Defined Identifier:</b>  <b>Test::</b> C Reactive Protein_PX329  <b>Result::</b> 0.78  <b>Not Done::</b></p>	<p>Initial Entry</p>

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Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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			<b>Lab Normal Range:</b> <i>Low</i> 0.0  <i>High</i> 0.9  <i>Unit</i> mg/dL	
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5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-05-2020 08:52:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 329	Initial Entry
Oct-05-2020 08:49:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 329	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C Reactive Protein_PX329	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Oct-05-2020 08:49:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0.78	Initial Entry

5.a Not Done:

5.a Not Done:				
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090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

Date	Location	User	Value	Reason
Oct-05-2020 08:52:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 0.0  <i>High</i> 0.9  <i>Unit</i> mg/dL	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-05-2020 08:49:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> : <b>Test::</b> Alanine Aminotransferase_PX30 <b>Result::</b> 70 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 10  <i>High</i> 44  <i>Unit</i> U/L	Transcription Error
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> :	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Test::</b> Alanine Aminotransferase_PX30	
			<b>Result::</b> 78	
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b> <i>Low</i>	
			10	
			<i>High</i>	
			44	
			<i>Unit</i>	
			U/L	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.b Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Alanine Aminotransferase_PX30	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Oct-05-2020 08:49:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 70	Transcription Error
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 78	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Low 10 High 44 Unit U/L	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-05-2020 08:49:57 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defi 28	Transcription Error

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

Time (US & Canada)			<b>ned Identifier</b> : <b>Test::</b> Aspartate Aminotransferase_PX28 <b>Result::</b> 28 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 10  <i>High</i> 40  <i>Unit</i> U/L	
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier</b> 28 : <b>Test::</b> Aspartate Aminotransferase_PX28 <b>Result::</b> 40 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 10  <i>High</i> 40  <i>Unit</i> U/L	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.c Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 28	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aspartate Aminotransferase_PX2 8	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Oct-05-2020 08:49:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 28	Transcription Error
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 40	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 10 <i>High</i> 40 <i>Unit</i> U/L	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-05-2020 08:50:26 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defin</b> 35	Transcription Error

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

Time (US & Canada)			<b>ed Identifier:</b> <b>Test::</b> Alkaline Phosphatase_PX35 <b>Result::</b> 60 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 55 <i>High</i> 135 <i>Unit</i> U/L	
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 35 <b>Test::</b> Alkaline Phosphatase_PX35 <b>Result::</b> 58 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 55 <i>High</i> 135 <i>Unit</i> U/L	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.d Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 35	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Alkaline Phosphatase_PX35	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Oct-05-2020 08:50:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 60	Transcription Error
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 58	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Low 55 High 135 Unit U/L	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-05-2020 08:50:54 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined I 21	Transcription Error

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

Time (US & Canada)			<b>dentifier:</b> <b>Test::</b> Bilirubin_P X21 <b>Result::</b> 0.3 <b>Not Done::</b> <b>Lab Normal Range</b> <i>Low</i> : 0.1  <i>High</i> 1.0  <i>Unit</i> mg/dL	
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined I</b> 21 <b>dentifier:</b> <b>Test::</b> Bilirubin_P X21 <b>Result::</b> 0.4 <b>Not Done::</b> <b>Lab Normal Range</b> <i>Low</i> : 0.1  <i>High</i> 1.0  <i>Unit</i> mg/dL	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.e Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 21	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Bilirubin_PX21	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Oct-05-2020 08:50:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0.3	Transcription Error
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0.4	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0.1 <i>High</i> 1.0 <i>Unit</i> mg/dL	Initial Entry

5.f

Date	Location	User	Value	Reason
Oct-05-2020 08:51:21 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defin 47	Transcription Error

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1235

**Subject No:** 12351071

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

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

Time (US & Canada)			<b>ed Identifier:</b> <b>Test::</b> Blood Urea Nitrogen_PX47 <b>Result::</b> 12 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 6  <i>High</i> 20  <i>Unit</i> mg/dL	
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 47 <b>Test::</b> Blood Urea Nitrogen_PX47 <b>Result::</b> 9 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 6  <i>High</i> 20  <i>Unit</i> mg/dL	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.f Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 47	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Blood Urea Nitrogen_PX47	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Oct-05-2020 08:51:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 12	Transcription Error
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 9	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Low 6  High 20  Unit mg/dL	Initial Entry

5.g

Date	Location	User	Value	Reason
Oct-05-2020 08:52:09 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined I 48	Transcription Error

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

Time (US & Canada)			<b>dentifier:</b> <b>Test::</b> Creatinine_ PX48 <b>Result::</b> 0.80 <b>Not Done::</b> <b>Lab Normal Rang</b> <i>Low</i> <b>e:</b> 0.50  <i>High</i> 1.40  <i>Unit</i> mg/dL	
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined I</b> 48 <b>dentifier:</b> <b>Test::</b> Creatinine_ PX48 <b>Result::</b> 0.77 <b>Not Done::</b> <b>Lab Normal Rang</b> <i>Low</i> <b>e:</b> 0.50  <i>High</i> 1.40  <i>Unit</i> mg/dL	Initial Entry

**5.g Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 48	Initial Entry

**5.g Test:**

Date	Location	User	Value	Reason
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Creatinine_PX48	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:51

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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**5.g Result:**

Date	Location	User	Value	Reason
Oct-05-2020 08:52:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0.80	Transcription Error
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0.77	Initial Entry

**5.g LNMT**

Date	Location	User	Value	Reason
Sep-29-2020 09:59:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0.50  <i>High</i> 1.40  <i>Unit</i> mg/dL	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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

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

**Form Status:**

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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

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Date	Location	User	Value	Reason
Oct-27-2020 12:49:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Oct-27-2020 12:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Oct-27-2020 12:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-27-2020 12:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Oct-27-2020 12:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-27-2020 12:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <b>Sponsor-Defined Identifier:</b> Not Done <b>Test::</b> Not Done <b>Result::</b> Not Done	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

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

			Not Done::	Not Done
			Lab Normal Range:	Not Done

5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-27-2020 12:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Oct-27-2020 12:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Oct-27-2020 12:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Oct-27-2020 12:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Oct-27-2020 12:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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

5.b

Date	Location	User	Value	Reason
Oct-27-2020 12:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done <b>Test::</b> Not Done <b>Result::</b> Not Done <b>Not Done::</b> Not Done <b>Lab Normal Range:</b> Not Done	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

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Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

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5.b Sponsor ID:

Date	Location	User	Value	Reason
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5.b Test:

Date	Location	User	Value	Reason
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5.b Result:

Date	Location	User	Value	Reason
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5.b Not Done:

Date	Location	User	Value	Reason
Oct-27-2020 12:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Oct-27-2020 12:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
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090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

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Time (US & Canada)			<b>ifier:</b>	ne	
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			<b>Not Done::</b>	Not Done	
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Header Text: c4591001

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Generated Time (GMT): 29-Mar-2021 19:09

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5.c Sponsor ID:

Date	Location	User	Value	Reason
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5.c Test:

Date	Location	User	Value	Reason
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5.c Result:

Date	Location	User	Value	Reason
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5.c Not Done:

Date	Location	User	Value	Reason
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5.c LNMT

Date	Location	User	Value	Reason
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5.d

Date	Location	User	Value	Reason
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090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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**Site Name:** (1235) LSU Health Shreveport

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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			<b>Not Done::</b>	Not Done	
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			<b>Lab Normal Range:</b>	Not Done	
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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Generated Time (GMT): 29-Mar-2021 19:09

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5.d Sponsor ID:

Date	Location	User	Value	Reason
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5.d Test:

Date	Location	User	Value	Reason
Oct-27-2020 12:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Oct-27-2020 12:49:03 (UTC-06:00) Central 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
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5.d LNMT

Date	Location	User	Value	Reason
Oct-27-2020 12:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.e

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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**Generated Time (GMT):** 29-Mar-2021 19:09

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			<b>Not Done::</b>	Not Done	
				ne	
			<b>Lab Normal Range:</b>	Not Done	
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Header Text: c4591001

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Date	Location	User	Value	Reason
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5.e Result:

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5.e LNMT

Date	Location	User	Value	Reason
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5.f

Date	Location	User	Value	Reason
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**Generated Time (GMT):** 29-Mar-2021 19:09

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			<b>Not Done::</b>	Not Done	
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			<b>Lab Normal Range:</b>	Not Done	
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5.f Not Done:

Date	Location	User	Value	Reason
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5.g

Date	Location	User	Value	Reason
Oct-27-2020 12:49:03 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Sponsor-Defined Ident</u> Not Do	Initial Entry

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5.h

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5.h LNMT

Date	Location	User	Value	Reason
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5.i

Date	Location	User	Value	Reason
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			<b>Not Done::</b>	Not Done	
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Date	Location	User	Value	Reason
Oct-27-2020 12:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

**5.i Result:**

Date	Location	User	Value	Reason
Oct-27-2020 12:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

**5.i Not Done:**

Date	Location	User	Value	Reason
Oct-27-2020 12:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

**5.i LNMT**

Date	Location	User	Value	Reason
Oct-27-2020 12:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

**5.j**

Date	Location	User	Value	Reason
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090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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

Oct-27-2020 12:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done <b>Test::</b> Not Done <b>Result::</b> Not Done <b>Not Done::</b> Not Done <b>Lab Normal Range:</b> Not Done	Initial Entry
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

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

5.j Sponsor ID:

Date	Location	User	Value	Reason
Oct-27-2020 12:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Oct-27-2020 12:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Oct-27-2020 12:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Oct-27-2020 12:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Oct-27-2020 12:49:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Sep/22/2020

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

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

**Form Status:**

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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

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

**Form Status:**

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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Date	Location	User	Value	Reason
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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

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

**Form Status:**

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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Date	Location	User	Value	Reason
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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

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

**Form Status:**

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> HEMATOLOGY	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Oct-16-2020 11:03:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-16-2020 09:10:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	done
Oct-15-2020 22:13:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 1: Reissued:Opened	Apologies, can you please update the lab name for all your entries on the HEMATOLOGY pages for this subject in this visit? Please do not copy and paste or use carriage returns in lab name entries as this causes a technical issue for us.
Oct-15-2020 13:19:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	done
Oct-15-2020 13:19:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport, LA 71103	done
Oct-15-2020 13:12:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	There is a invalid character (Carriage returns) found in the

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

				lab name and address field. Please re-enter the lab name and address with out adding spaces before and after term and without pressing enter key. Please do update for all labs in the CRF.
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport. LA 71103	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/23/2020	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLOOD	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Hemoglobin _PX1 <b>Result::</b> 13.8 <b>Not Done::</b>	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

			<b>Lab Normal Range</b> <i>Low</i> : 12.5  <i>High</i> 16.3  <i>Unit</i> g/dL	
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5.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hemoglobin_PX1	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 13.8	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 12.5  <i>High</i> 16.3  <i>Unit</i> g/dL	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

**5.b**

Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Id 2 entifier:</b> <b>Test::</b> Hematocrit_ PX2 <b>Result::</b> 40.5 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 36.7  <i>High</i> 47.1  <i>Unit</i> %	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen, Verified**Site No:** 1235**Site Name:** (1235) LSU Health Shreveport**Subject No:** 12351071**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**5.b Test:**

Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hematocrit_PX2	Initial Entry

**5.b Result:**

Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 40.5	Initial Entry

**5.b LNMT**

Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 36.7  <i>High</i> 47.1  <i>Unit</i> %	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Nov-02-2020 09:24:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined I 3</b> <b>dentifier:</b>  <b>Test::</b> Erythrocytes _PX3	Transcription Error

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Result::</b> 4.20 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 4.6 <i>High</i> 6.2 <i>Unit</i> 10 <sup>12</sup> /L	
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Erythrocytes _PX3 <b>Result::</b> 4.20 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 4.6 <i>High</i> 6.2 <i>Unit</i> 10 <sup>9</sup> /L	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.c Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Erythrocytes_PX3	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Nov-03-2020 21:37:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Nov-02-2020 09:24:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	updated
Oct-30-2020 12:07:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Please the Unit should be << 10^6/uL OR 10^12/L >> and update as appropriate
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4.20	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Nov-02-2020 09:24:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Low 4.6  High	Transcription Error

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			6.2 <i>Unit</i> 10 <sup>12</sup> /L	
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 4.6  <i>High</i> 6.2  <i>Unit</i> 10 <sup>9</sup> /L	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 5 <b>Test::</b> Platelets_P X5 <b>Result::</b> 224 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 150  <i>High</i> 350  <i>Unit</i> 10 <sup>3</sup> /uL	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Sep/22/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.d Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Platelets_PX5	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 224	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 150  <i>High</i> 350  <i>Unit</i> 10^3/uL	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Id</b> 7 <b>entifier:</b> <b>Test::</b> Leukocytes_ PX7	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Result::</b> 5.03	
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b> <i>Low</i>	
			3.9	
			<i>High</i>	
			12.70	
			<i>Unit</i>	
			10 <sup>3</sup> /uL	

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen, Verified**Site No:** 1235**Site Name:** (1235) LSU Health Shreveport**Subject No:** 12351071**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

**5.e Test:**

Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Leukocytes_PX7	Initial Entry

**5.e Result:**

Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 5.03	Initial Entry

**5.e LNMT**

Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 3.9  <i>High</i> 12.70  <i>Unit</i> 10 <sup>3</sup> /uL	Initial Entry

**5.f**

Date	Location	User	Value	Reason
Oct-05-2020 09:09:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined</b> 608 <b>Identifier:</b> <b>Test::</b> Neutrophils_ PX608	Changed Information

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Result::</b> 2.4 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 1.8  <i>High</i> 7.7  <i>Unit</i> 10 <sup>3</sup> /uL	
Oct-05-2020 09:08:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 608 <b>Test::</b> Neutrophils_PX608 <b>Result::</b> 2.4 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 38  <i>High</i> 73  <i>Unit</i> %	Changed Information
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 608 <b>Test::</b> Neutrophils_PX608 <b>Result::</b> 48.3 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 38  <i>High</i> 73  <i>Unit</i> %	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Sep/22/2020

Form Version: 15-Sep-2020 21:55

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Site No: 1235

Site Name: (1235) LSU Health Shreveport

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.f Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 608	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Neutrophils_PX608	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Oct-05-2020 14:50:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_LB001_08
Oct-05-2020 09:08:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-05-2020 09:08:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2.4	Changed Information
Oct-03-2020 00:25:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: As per CRF Completion Requirements WBC differentials should be entered as absolute values using 10 <sup>9</sup> /L as units. Please

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

				confirm that absolute values are not provided on the lab report, or update as appropriate.
Sep-30-2020 14:30:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	All values and normal ranges are provided in percentages. This pertains to all differentials for all heme data.
Sep-30-2020 05:22:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4845399;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 48.3	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Oct-05-2020 09:09:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Low 1.8  High 7.7  Unit 10 <sup>3</sup> /uL	Changed Information
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Low 38	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

			High 73	
			Unit %	

5.g

Date	Location	User	Value	Reason
Oct-05-2020 09:12:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 609 <b>Test::</b> Eosinophils_PX609 <b>Result::</b> 0.0 <b>Not Done::</b> <b>Lab Normal Range:</b> Low 0.0 High 0.5 Unit 10^3/uL	Changed Information
Oct-05-2020 09:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 609 <b>Test::</b> Eosinophils_PX609 <b>Result::</b> 0.0 <b>Not Done::</b> <b>Lab Normal Range:</b> Low 0 High 8.0 Unit %	Changed Information
Sep-29-2020 10:15:32 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined</b> 609	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

Time (US & Canada)			<b>Identifier:</b> <b>Test::</b> Eosinophils_PX609 <b>Result::</b> 0.6 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0 <i>High</i> 8.0 <i>Unit</i> %	
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5.g Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 609	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Eosinophils_PX609	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Oct-05-2020 14:50:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_LB001_08

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

[Back to Form](#)

5.g Result:

Date	Location	User	Value	Reason
Oct-05-2020 09:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swere d	Changed Information
Oct-05-2020 09:11:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b>  : 0.0	Changed Information
Oct-03-2020 03:52:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Rei ssued: Opene d	DM: As per CRF Completion Requirements WBC differentials should be entered as absolute values using 10 <sup>9</sup> /L as units. Please confirm that absolute values are not provided on the lab report or update as appropriate.
Oct-02-2020 15:43:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: An swere d	values entered as percentages. Ranges entered as percentages.
Sep-30-2020 05:21:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW4845397;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

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Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : 0.6	Initial Entry
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5.g LNMT

Date	Location	User	Value	Reason
Oct-05-2020 09:12:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0.0  <i>High</i> 0.5  <i>Unit</i> 10 <sup>3</sup> /uL	Changed Information
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0  <i>High</i> 8.0  <i>Unit</i> %	Initial Entry

5.h

Date	Location	User	Value	Reason
Oct-05-2020 09:16:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Monocytes_PX612 <b>Result::</b> 1.1 <b>Not Done::</b>	Changed Information

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

			<b>Lab Normal Range:</b> <i>Low</i> : 0.3  <i>High</i> : 1.0  <i>Unit</i> : 10 <sup>3</sup> /uL	
Oct-05-2020 09:15:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 612 <b>Test::</b> Monocytes_PX612 <b>Result::</b> 1.1 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> : 4.0  <i>High</i> : 15.0  <i>Unit</i> : %	Changed Information
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 612 <b>Test::</b> Monocytes_PX612 <b>Result::</b> 22.3 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> : 4.0  <i>High</i> : 15.0  <i>Unit</i> : %	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Sep/22/2020

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.h Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 612	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Monocytes_PX612	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Oct-05-2020 14:50:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_LB001_08
Oct-05-2020 09:15:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-05-2020 09:15:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1.1	Changed Information
Oct-03-2020 03:56:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: As per CRF Completion Requirements WBC differentials should be entered as absolute values using 10 <sup>9</sup> /L as units. Please

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

				confirm that absolute values are not provided on the lab report or update as appropriate.
Oct-02-2020 15:44:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Ranges and values entered in percentages.
Sep-30-2020 05:41:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4845429;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 22.3	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Oct-05-2020 09:16:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Low 0.3  High 1.0  Unit 10^3/uL	Changed Information
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Low 4.0	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

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Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

			High 15.0	
			Unit %	

5.i

Date	Location	User	Value	Reason
Oct-05-2020 09:17:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 610 <b>Test::</b> Basophils_P X610 <b>Result::</b> 0.03 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0.0 <i>High</i> 0.20 <i>Unit</i> 10^3/uL	Changed Information
Oct-05-2020 09:16:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 610 <b>Test::</b> Basophils_P X610 <b>Result::</b> 0.03 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0.0 <i>High</i> 1.9 <i>Unit</i> %	Changed Information
Sep-29-2020 10:15:32 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 610	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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**Site No:** 1235

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**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

Time (US & Canada)			<b>dentifier:</b>	
			<b>Test::</b>	Basophils_P X610
			<b>Result::</b>	0.6
			<b>Not Done::</b>	
			<b>Lab Normal Rang</b>	<i>Low</i>
			<b>e:</b>	0.0
				<i>High</i>
				1.9
				<i>Unit</i>
				%

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.i Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 610	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Basophils_PX610	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Oct-05-2020 14:50:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_LB001_08
Oct-05-2020 09:16:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-05-2020 09:16:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 0.03	Changed Information
Oct-03-2020 00:27:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: As per CRF Completion Requirements WBC differentials should be entered as absolute values using 10 <sup>9</sup> /L as units. Please

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen, Verified**Site No:** 1235**Site Name:** (1235) LSU Health Shreveport**Subject No:** 12351071**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09

				confirm that absolute values are not provided on the lab report, or update as appropriate.
Oct-02-2020 15:44:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Ranges and values entered in percentages.
Sep-30-2020 05:42:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4845431;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0.6	Initial Entry

**5.i LNMT**

Date	Location	User	Value	Reason
Oct-05-2020 09:17:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0.0  <i>High</i> 0.20  <i>Unit</i> 10 <sup>3</sup> /uL	Changed Information
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0.0	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

			High 1.9	
			Unit %	

5.j

Date	Location	User	Value	Reason
Oct-05-2020 09:18:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 611 <b>Test::</b> Lymphocytes _PX611 <b>Result::</b> 1.4 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 1.0  <i>High</i> 4.8  <i>Unit</i> 10^3/uL	Changed Information
Oct-05-2020 09:17:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 611 <b>Test::</b> Lymphocytes _PX611 <b>Result::</b> 1.4 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 18.0  <i>High</i> 48.0  <i>Unit</i> %	Changed Information
Sep-29-2020 10:15:32 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined</b> 611	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

Time (US & Canada)			<b>Identifier:</b> <b>Test::</b> Lymphocytes _PX611 <b>Result::</b> 28.2 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 18.0 <i>High</i> 48.0 <i>Unit</i> %	
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1235

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Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.j Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 611	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Lymphocytes_PX611	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Oct-05-2020 14:50:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_LB001_08
Oct-05-2020 09:17:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-05-2020 09:17:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1.4	Changed Information
Oct-03-2020 00:27:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: As per CRF Completion Requirements WBC differentials should be entered as absolute values using 10 <sup>9</sup> /L as units. Please

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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Site No: 1235

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				confirm that absolute values are not provided on the lab report, or update as appropriate.
Oct-02-2020 15:45:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Ranges and values entered in percentages.
Sep-30-2020 05:38:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4845435;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 28.2	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Oct-05-2020 09:18:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Low 1.0  High 4.8  Unit 10^3/uL	Changed Information
Sep-29-2020 10:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Low 18.0	Initial Entry

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

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**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<i>High</i> 48.0	
			<i>Unit</i> %	

**Header Text:** c4591001

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-29-2020 10:20:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> HEMATOLOGY	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Oct-16-2020 16:11:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 1: Closed	Response satisfies query
Oct-16-2020 15:57:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport, L A 71103	query
Oct-16-2020 14:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	done
Oct-16-2020 14:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport, LA 71103	done
Oct-16-2020 13:17:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	There is a invalid character (Carriage returns) found in the lab name and address field. Please re-enter the lab name and address with out adding spaces before and after term and without pressing enter key.
Oct-16-2020 09:10:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ochsner LSU Health Shreveport 1501 Kings Hwy	query response

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Header Text: c4591001

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Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

			Shreveport,LA 71103	
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ochnser LSU Health Shreveport 1501 Kings Hwy Shreveport, LA 71103	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-29-2020 10:20:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/24/2020	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Sep-29-2020 10:20:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLOOD	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Id 1 entifier:</b> <b>Test::</b> Hemoglobin _PX1 <b>Result::</b> 13.1 <b>Not Done::</b> <b>Lab Normal Range</b> <i>Low</i> : 12.5  <i>High</i> 16.3  <i>Unit</i> g/dL	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
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Header Text: c4591001

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Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry
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5.a Test:

Date	Location	User	Value	Reason
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hemoglobin_PX1	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 13.1	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 12.5  <i>High</i> 16.3  <i>Unit</i> g/dL	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Id 2</b> <b>entifier:</b> <b>Test::</b> Hematocrit_ PX2 <b>Result::</b> 39.1 <b>Not Done::</b>	Initial Entry

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Header Text: c4591001

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Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

			<b>Lab Normal Range:</b> <i>Low</i> 36.7  <i>High</i> 47.1  <i>Unit</i> %	
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5.b Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hematocrit_PX2	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 39.1	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 36.7  <i>High</i> 47.1  <i>Unit</i> %	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

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5.c

Date	Location	User	Value	Reason
Nov-02-2020 09:25:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined I 3 dentifier:</b> <b>Test::</b> Erythrocytes _PX3 <b>Result::</b> 4.07 <b>Not Done::</b> <b>Lab Normal Rang Low e:</b> 4.6  <i>High</i> 6.2  <i>Unit</i> 10^12/L	Transcription Error
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined I 3 dentifier:</b> <b>Test::</b> Erythrocytes _PX3 <b>Result::</b> 4.07 <b>Not Done::</b> <b>Lab Normal Rang Low e:</b> 4.6  <i>High</i> 6.2  <i>Unit</i> /uL	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.c Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Erythrocytes_PX3	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Nov-03-2020 21:37:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Nov-02-2020 09:25:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	updated
Oct-30-2020 12:06:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Please the Unit should be << 10^6/uL OR 10^12/L >> and update as appropriate
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4.07	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Nov-02-2020 09:25:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Low 4.6  High	Transcription Error

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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			6.2 <i>Unit</i> 10 <sup>12</sup> /L	
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 4.6  <i>High</i> 6.2  <i>Unit</i> /uL	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 5 <b>Test::</b> Platelets_P X5 <b>Result::</b> 199 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 150  <i>High</i> 350  <i>Unit</i> 10 <sup>3</sup> /uL	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen, Verified**Site No:** 1235**Site Name:** (1235) LSU Health Shreveport**Subject No:** 12351071**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

**5.d Test:**

Date	Location	User	Value	Reason
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Platelets_PX5	Initial Entry

**5.d Result:**

Date	Location	User	Value	Reason
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 199	Initial Entry

**5.d LNMT**

Date	Location	User	Value	Reason
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 150  <i>High</i> 350  <i>Unit</i> 10 <sup>3</sup> /uL	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Id 7</b> <b>entifier:</b> <b>Test::</b> Leukocytes_ PX7	Initial Entry

**Header Text:** c4591001

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**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Result::</b> 4.01	
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b> <i>Low</i>	
			3.9	
			<i>High</i>	
			12.7	
			<i>Unit</i>	
			10 <sup>3</sup> /uL	

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen, Verified**Site No:** 1235**Site Name:** (1235) LSU Health Shreveport**Subject No:** 12351071**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

**5.e Test:**

Date	Location	User	Value	Reason
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Leukocytes_PX7	Initial Entry

**5.e Result:**

Date	Location	User	Value	Reason
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4.01	Initial Entry

**5.e LNMT**

Date	Location	User	Value	Reason
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 3.9  <i>High</i> 12.7  <i>Unit</i> 10 <sup>3</sup> /uL	Initial Entry

**5.f**

Date	Location	User	Value	Reason
Oct-05-2020 09:21:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined</b> 608 <b>Identifier:</b> <b>Test::</b> Neutrophils_ PX608	Changed Information



Header Text: c4591001

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Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

			<b>Result::</b> 1.4 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 1.8  <i>High</i> 7.7  <i>Unit</i> 10 <sup>3</sup> /uL	
Oct-05-2020 09:20:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 608 <b>Test::</b> Neutrophils_PX608 <b>Result::</b> 1.4 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 38  <i>High</i> 73  <i>Unit</i> %	Changed Information
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 608 <b>Test::</b> Neutrophils_PX608 <b>Result::</b> 35.2 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 38  <i>High</i> 73  <i>Unit</i> %	Initial Entry

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Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.f Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 608	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Neutrophils_PX608	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Oct-05-2020 14:50:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_LB001_08
Oct-05-2020 09:20:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-05-2020 09:20:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1.4	Changed Information
Oct-03-2020 11:58:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: Thanks for response. However as per CRF Completion Requirements manually converted WBC differentials from % to absolute

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

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				that do not appear on the lab report. Kindly consider updating the values as per CCG in Logline #3 to #5 as appropriate.
Oct-02-2020 15:45:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Ranges and values entered in percentages.
Sep-30-2020 05:42:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4845432;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 35.2	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Oct-05-2020 09:21:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Low 1.8  High 7.7  Unit 10 <sup>3</sup> /uL	Changed Information
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Low 38	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

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			High 73	
			Unit %	

5.g

Date	Location	User	Value	Reason
Oct-05-2020 09:21:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 609 <b>Test::</b> Eosinophils_PX609 <b>Result::</b> 0.1 <b>Not Done::</b> <b>Lab Normal Range:</b> Low 0.0 High 0.5 Unit 10^3/uL	Changed Information
Oct-05-2020 09:21:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 609 <b>Test::</b> Eosinophils_PX609 <b>Result::</b> 0.1 <b>Not Done::</b> <b>Lab Normal Range:</b> Low 0 High 0.8 Unit %	Changed Information
Sep-29-2020 10:19:57	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

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Header Text: c4591001

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Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

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(UTC-06:00) Central Time (US & Canada)		(autocalc)	<b>Sponsor-Defined Identifier:</b> <b>Test::</b> Eosinophils_PX609 <b>Result::</b> 1.5 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0 <i>High</i> 0.8 <i>Unit</i> %	
--	--	------------	--	--

5.g Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 609	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Eosinophils_PX609	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Oct-05-2020 09:21:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0.1	Changed Information

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Header Text: c4591001

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Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

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**5.g Result:**

Date	Location	User	Value	Reason
Oct-03-2020 11:59:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-02-2020 15:45:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Ranges and values entered in percentages.
Sep-30-2020 05:39:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4845434;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> 1.5	Initial Entry

**5.g LNMT**

Date	Location	User	Value	Reason
Oct-05-2020 09:21:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0.0  <i>High</i> 0.5	Changed Information

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

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			Unit 10^3/uL	
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0  <i>High</i> 0.8  <i>Unit</i> %	Initial Entry

5.h

Date	Location	User	Value	Reason
Oct-05-2020 09:23:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Monocytes_ PX612 <b>Result::</b> 0.8 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0.3  <i>High</i> 1.0  <i>Unit</i> 10^3/uL	Changed Information
Oct-05-2020 09:22:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 612 <b>Test::</b> Monocytes_ PX612 <b>Result::</b> 0.8 <b>Not Done::</b>	Changed Information

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Lab Normal Range:</b> <i>Low</i> 4.0 <i>High</i> 15.0 <i>Unit</i> %	
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 612 <b>Test::</b> Monocytes_PX612 <b>Result::</b> 20.9 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 4.0 <i>High</i> 15.0 <i>Unit</i> %	Initial Entry

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Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.h Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 612	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Monocytes_PX612	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Oct-05-2020 09:22:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 0.8	Changed Information
Oct-03-2020 11:59:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-02-2020 15:46:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Ranges and values entered in percentages.
Sep-30-2020 05:20:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4845395;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as

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Subject Initials: ---

Generated By: (b) (4)

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				appropriate.
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 20.9	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Oct-05-2020 09:23:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0.3  <i>High</i> 1.0  <i>Unit</i> 10 <sup>3</sup> /uL	Changed Information
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 4.0  <i>High</i> 15.0  <i>Unit</i> %	Initial Entry

5.i

Date	Location	User	Value	Reason
Oct-05-2020 09:23:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Basophils_P X610 <b>Result::</b> 0.02 <b>Not Done::</b>	Changed Information

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Lab Normal Range:</b> <i>Low</i> 0.0  <i>High</i> 0.2  <i>Unit</i> 10 <sup>3</sup> /uL	
Oct-05-2020 09:23:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 610 <b>Test::</b> Basophils_P X610 <b>Result::</b> 0.02 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0.0  <i>High</i> 1.9  <i>Unit</i> %	Changed Information
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 610 <b>Test::</b> Basophils_P X610 <b>Result::</b> 0.5 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0.0  <i>High</i> 1.9  <i>Unit</i> %	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History  
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**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

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**5.i Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 610	Initial Entry

**5.i Test:**

Date	Location	User	Value	Reason
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Basophils_PX610	Initial Entry

**5.i Result:**

Date	Location	User	Value	Reason
Oct-05-2020 09:23:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0.02	Changed Information
Oct-03-2020 11:59:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-02-2020 15:46:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Ranges and values entered in percentages.
Sep-30-2020 05:16:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4845392;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as

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Header Text: c4591001

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Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

				appropriate.
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0.5	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Oct-05-2020 09:23:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0.0  <i>High</i> 0.2  <i>Unit</i> 10 <sup>3</sup> /uL	Changed Information
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0.0  <i>High</i> 1.9  <i>Unit</i> %	Initial Entry

5.j

Date	Location	User	Value	Reason
Oct-05-2020 09:24:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 611 <b>Test::</b> Lymphocytes_PX611 <b>Result::</b> 1.7 <b>Not Done::</b>	Changed Information

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Lab Normal Range:</b> <i>Low</i> 1.0  <i>High</i> 4.8  <i>Unit</i> 10 <sup>3</sup> /uL	
Oct-05-2020 09:24:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 611 <b>Test::</b> Lymphocytes_PX611 <b>Result::</b> 1.7 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 18.0  <i>High</i> 48.0  <i>Unit</i> %	Changed Information
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 611 <b>Test::</b> Lymphocytes_PX611 <b>Result::</b> 41.9 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 18.0  <i>High</i> 48.0  <i>Unit</i> %	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Sep/22/2020

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

**5.j Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 611	Initial Entry

**5.j Test:**

Date	Location	User	Value	Reason
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Lymphocytes_PX611	Initial Entry

**5.j Result:**

Date	Location	User	Value	Reason
Oct-05-2020 09:24:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1.7	Changed Information
Oct-03-2020 11:59:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-02-2020 15:46:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Ranges and values entered in percentages.
Sep-30-2020 05:14:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4845389;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as

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**Site No:** 1235

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**Subject Initials:** ---

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				appropriate.
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 41.9	Initial Entry

**5.j LNMT**

Date	Location	User	Value	Reason
Oct-05-2020 09:24:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 1.0  <i>High</i> 4.8  <i>Unit</i> 10 <sup>3</sup> /uL	Changed Information
Sep-29-2020 10:19:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 18.0  <i>High</i> 48.0  <i>Unit</i> %	Initial Entry

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> HEMATOLOGY	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Oct-16-2020 16:11:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 1: Closed	Response satisfies query
Oct-16-2020 15:57:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport, L A 71103	query
Oct-16-2020 14:12:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	done
Oct-16-2020 14:12:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport, LA 71103	done
Oct-16-2020 13:18:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	There is a invalid character (Carriage returns) found in the lab name and address field. Please re-enter the lab name and address with out adding spaces before and after term and without pressing enter key.
Oct-16-2020 09:11:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ochsner LSU Health Shreveport 1501 Kings Hwy	query response

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Subject Initials: ---

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			Shreveport,LA 71103	
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport, LA 71103	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/25/2020	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLOOD	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Hemoglobin _PX1 <b>Result::</b> 14.3 <b>Not Done::</b> <b>Lab Normal Range</b> <i>Low</i> : 12.5  <i>High</i> 16.3  <i>Unit</i> g/dL	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
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Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry
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5.a Test:

Date	Location	User	Value	Reason
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hemoglobin_PX1	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 14.3	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 12.5  <i>High</i> 16.3  <i>Unit</i> g/dL	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-12-2020 10:37:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined I 2 dentifier:</b> <b>Test::</b> Hematocrit _PX2 <b>Result::</b> 42.2 <b>Not Done::</b>	Transcription Error

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			<b>Lab Normal Range:</b> <i>Low</i> 36.7  <i>High</i> 47.1  <i>Unit</i> %	
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Hematocrit _PX2 <b>Result::</b> 42.2 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 36.7  <i>High</i> 47.1  <i>Unit</i> g/dL	Initial Entry

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Site Name: (1235) LSU Health Shreveport

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Subject Initials: ---

Generated By: (b) (4)

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5.b Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hematocrit_PX2	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Nov-13-2020 00:50:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Nov-12-2020 10:37:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	corrected
Nov-12-2020 07:20:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Please the Hematocrit Unit should be "%" and not "g/dL". Please update accordingly
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 42.2	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Nov-12-2020 10:37:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Low 36.7  High 47.1	Transcription Error

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			Unit %	
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 36.7  <i>High</i> 47.1  <i>Unit</i> g/dL	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-02-2020 09:26:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined I 3 dentifier:</b> <b>Test::</b> Erythrocytes _PX3 <b>Result::</b> 4.40 <b>Not Done::</b> <b>Lab Normal Rang</b> <i>Low</i> <b>e:</b> 4.6  <i>High</i> 6.2  <i>Unit</i> 10^12/L	Transcription Error
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined I 3 dentifier:</b> <b>Test::</b> Erythrocytes _PX3 <b>Result::</b> 4.40 <b>Not Done::</b>	Initial Entry

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

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			<b>Lab Normal Range:</b>	
			<i>Low</i>	
			4.6	
			<i>High</i>	
			6.2	
			<i>Unit</i>	
			10 <sup>9</sup> /L	

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Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

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5.c Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Erythrocytes_PX3	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Nov-03-2020 21:36:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Nov-02-2020 09:26:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	updated
Oct-30-2020 12:08:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Please the Unit should be << 10^6/uL OR 10^12/L >> and update as appropriate
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4.40	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Nov-02-2020 09:26:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Low 4.6  High	Transcription Error

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			6.2 <i>Unit</i> 10 <sup>12</sup> /L	
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 4.6  <i>High</i> 6.2  <i>Unit</i> 10 <sup>9</sup> /L	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 5 <b>Test::</b> Platelets_P X5 <b>Result::</b> 217 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 150  <i>High</i> 350  <i>Unit</i> 10 <sup>3</sup> /uL	Initial Entry

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Date	Location	User	Value	Reason
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

**5.d Test:**

Date	Location	User	Value	Reason
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Platelets_PX5	Initial Entry

**5.d Result:**

Date	Location	User	Value	Reason
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 217	Initial Entry

**5.d LNMT**

Date	Location	User	Value	Reason
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 150  <i>High</i> 350  <i>Unit</i> 10 <sup>3</sup> /uL	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Id 7 entifier:</b> <b>Test::</b> Leukocytes_ PX7	Initial Entry

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**Subject Initials:** ---

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

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			<b>Result::</b> 4.11	
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b> <i>Low</i>	
			3.9	
			<i>High</i>	
			12.7	
			<i>Unit</i>	
			10 <sup>3</sup> /uL	

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Date	Location	User	Value	Reason
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

**5.e Test:**

Date	Location	User	Value	Reason
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Leukocytes_PX7	Initial Entry

**5.e Result:**

Date	Location	User	Value	Reason
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4.11	Initial Entry

**5.e LNMT**

Date	Location	User	Value	Reason
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 3.9  <i>High</i> 12.7  <i>Unit</i> 10 <sup>3</sup> /uL	Initial Entry

**5.f**

Date	Location	User	Value	Reason
Oct-05-2020 09:26:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined</b> 608 <b>Identifier:</b> <b>Test::</b> Neutrophils_ PX608	Changed Information

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**Subject Initials:** ---

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

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			<b>Result::</b> 1.1 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 1.8  <i>High</i> 7.7  <i>Unit</i> 10 <sup>3</sup> /uL	
Oct-05-2020 09:26:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 608 <b>Test::</b> Neutrophils_PX608 <b>Result::</b> 1.1 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 38  <i>High</i> 73  <i>Unit</i> %	Changed Information
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 608 <b>Test::</b> Neutrophils_PX608 <b>Result::</b> 27.5 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 38  <i>High</i> 73  <i>Unit</i> %	Initial Entry

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Generated By: (b) (4)

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5.f Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 608	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Neutrophils_PX608	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Oct-05-2020 09:26:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1.1	Changed Information
Oct-03-2020 12:08:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-02-2020 15:46:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Ranges and values entered in percentages.
Sep-30-2020 05:12:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4845387;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

				appropriate.
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 27.5	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Oct-05-2020 09:26:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 1.8  <i>High</i> 7.7  <i>Unit</i> 10 <sup>3</sup> /uL	Changed Information
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 38  <i>High</i> 73  <i>Unit</i> %	Initial Entry

5.g

Date	Location	User	Value	Reason
Oct-05-2020 09:27:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 609 <b>Test::</b> Eosinophils_PX609 <b>Result::</b> 0.1 <b>Not Done::</b>	Changed Information

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Lab Normal Range:</b> <i>Low</i> 0.0  <i>High</i> 0.5  <i>Unit</i> 10 <sup>3</sup> /uL	
Oct-05-2020 09:27:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 609 <b>Test::</b> Eosinophils_PX609 <b>Result::</b> 0.1 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0.0  <i>High</i> 8.0  <i>Unit</i> %	Changed Information
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 609 <b>Test::</b> Eosinophils_PX609 <b>Result::</b> 2.2 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0.0  <i>High</i> 8.0  <i>Unit</i> %	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

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5.g Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 609	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Eosinophils_PX609	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Oct-05-2020 09:27:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0.1	Changed Information
Oct-03-2020 12:08:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-02-2020 15:47:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Ranges and values entered in percentages.
Sep-30-2020 05:40:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4845423;Please confirm that the WBC differentials are entered as absolute values instead of

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

Canada)				percentages, or correct as appropriate.
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2.2	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Oct-05-2020 09:27:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0.0  <i>High</i> 0.5  <i>Unit</i> 10 <sup>3</sup> /uL	Changed Information
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0.0  <i>High</i> 8.0  <i>Unit</i> %	Initial Entry

5.h

Date	Location	User	Value	Reason
Oct-05-2020 09:28:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Monocytes_PX612 <b>Result::</b> 0.6 <b>Not Done::</b>	Changed Information

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Lab Normal Range:</b> <i>Low</i> 0.3  <i>High</i> 1.0  <i>Unit</i> 10 <sup>3</sup> /uL	
Oct-05-2020 09:28:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 612 <b>Test::</b> Monocytes_ PX612 <b>Result::</b> 0.6 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 4.0  <i>High</i> 15.0  <i>Unit</i> %	Changed Information
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 612 <b>Test::</b> Monocytes_ PX612 <b>Result::</b> 14.8 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 4.0  <i>High</i> 15.0  <i>Unit</i> %	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Sep/22/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.h Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 612	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Monocytes_PX612	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Oct-05-2020 09:28:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 0.6	Changed Information
Oct-03-2020 12:08:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-02-2020 15:47:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Ranges and values entered in percentages.
Sep-30-2020 05:40:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4845425;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

				appropriate.
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 14.8	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Oct-05-2020 09:28:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0.3  <i>High</i> 1.0  <i>Unit</i> 10^3/uL	Changed Information
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 4.0  <i>High</i> 15.0  <i>Unit</i> %	Initial Entry

5.i

Date	Location	User	Value	Reason
Oct-05-2020 09:29:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Basophils_P X610 <b>Result::</b> 0.02 <b>Not Done::</b>	Changed Information

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Lab Normal Range:</b> <i>Low</i> 0.0  <i>High</i> 0.20  <i>Unit</i> 10 <sup>3</sup> /uL	
Oct-05-2020 09:28:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 610 <b>Test::</b> Basophils_P X610 <b>Result::</b> 0.02 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0.0  <i>High</i> 1.9  <i>Unit</i> %	Changed Information
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 610 <b>Test::</b> Basophils_P X610 <b>Result::</b> 0.5 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0.0  <i>High</i> 1.9  <i>Unit</i> %	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

**5.i Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 610	Initial Entry

**5.i Test:**

Date	Location	User	Value	Reason
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Basophils_PX610	Initial Entry

**5.i Result:**

Date	Location	User	Value	Reason
Oct-05-2020 09:28:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0.02	Changed Information
Oct-03-2020 12:11:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Queried at Logline #03
Oct-02-2020 15:47:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Ranges and values entered in percentages.
Sep-30-2020 05:40:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4845427;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

				appropriate.
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0.5	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Oct-05-2020 09:29:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0.0  <i>High</i> 0.20  <i>Unit</i> 10 <sup>3</sup> /uL	Changed Information
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0.0  <i>High</i> 1.9  <i>Unit</i> %	Initial Entry

5.j

Date	Location	User	Value	Reason
Oct-05-2020 09:30:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 611 <b>Test::</b> Lymphocytes_PX611 <b>Result::</b> 2.3 <b>Not Done::</b>	Changed Information

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Lab Normal Range:</b> <i>Low</i> 1.0  <i>High</i> 4.8  <i>Unit</i> 10^3/uL	
Oct-05-2020 09:29:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 611 <b>Test::</b> Lymphocytes_PX611 <b>Result::</b> 2.3 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 18.0  <i>High</i> 48.0  <i>Unit</i> %	Changed Information
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 611 <b>Test::</b> Lymphocytes_PX611 <b>Result::</b> 55 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 18.0  <i>High</i> 48.0  <i>Unit</i> %	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History  
on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

**5.j Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 611	Initial Entry

**5.j Test:**

Date	Location	User	Value	Reason
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Lymphocytes_PX611	Initial Entry

**5.j Result:**

Date	Location	User	Value	Reason
Oct-05-2020 09:29:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2.3	Changed Information
Oct-03-2020 12:11:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Queried at Logline #03
Oct-02-2020 15:47:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	Ranges and values entered in percentages.
Sep-30-2020 05:41:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Ope ned	DMW4845428;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

				appropriate.
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 55	Initial Entry

**5.j LNMT**

Date	Location	User	Value	Reason
Oct-05-2020 09:30:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 1.0  <i>High</i> 4.8  <i>Unit</i> 10 <sup>3</sup> /uL	Changed Information
Sep-29-2020 10:24:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 18.0  <i>High</i> 48.0  <i>Unit</i> %	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> HEMATOLOGY	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Oct-16-2020 16:11:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 1: Closed	Response satisfies query
Oct-16-2020 15:58:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport, L A 71103	query
Oct-16-2020 14:13:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	done
Oct-16-2020 14:13:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport, LA 71103	done
Oct-16-2020 13:18:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	There is a invalid character (Carriage returns) found in the lab name and address field. Please re-enter the lab name and address with out adding spaces before and after term and without pressing enter key.
Oct-16-2020 09:11:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ochsner LSU Health Shreveport 1501 Kings Hwy	query response

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

			Shreveport,LA 71103	
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ochsner LSU Health Shreveport 1501 Kings Hwy Shreveport LA 71103	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/26/2020	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLOOD	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Id 1</b> <b>entifier:</b> <b>Test::</b> Hemoglobin _PX1 <b>Result::</b> 14.0 <b>Not Done::</b> <b>Lab Normal Range</b> <i>Low</i> : 12.5  <i>High</i> 16.3  <i>Unit</i> g/dL	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
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090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Sep/22/2020

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry
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5.a Test:

Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hemoglobin_PX1	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 14.0	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 12.5  <i>High</i> 16.3  <i>Unit</i> g/dL	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Id 2</b> <b>entifier:</b> <b>Test::</b> Hematocrit_ PX2 <b>Result::</b> 41.1 <b>Not Done::</b>	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

			<b>Lab Normal Range:</b> <i>Low</i> 36.7  <i>High</i> 47.1  <i>Unit</i> %	
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5.b Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hematocrit_PX2	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 41.1	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 36.7  <i>High</i> 47.1  <i>Unit</i> %	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.c

Date	Location	User	Value	Reason
Nov-02-2020 09:26:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Erythrocytes _PX3 <b>Result::</b> 4.33 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 4.6  <i>High</i> 6.2  <i>Unit</i> 10^12/L	Transcription Error
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Erythrocytes _PX3 <b>Result::</b> 4.33 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 4.6  <i>High</i> 6.2  <i>Unit</i> 10^9/L	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.c Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 3	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Erythrocytes_PX3	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 4.33	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Nov-02-2020 09:26:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <i>Low</i> 4.6  <i>High</i> 6.2  <i>Unit</i> 10 <sup>12</sup> /L	Transcription Error
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <i>Low</i> 4.6  <i>High</i> 6.2  <i>Unit</i> 10 <sup>9</sup> /L	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

5.d

Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 5 <b>Test::</b> Platelets_P X5 <b>Result::</b> 211 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 150  <i>High</i> 350  <i>Unit</i> 10 <sup>3</sup> /uL	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.d Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Platelets_PX5	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 211	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 150  <i>High</i> 350  <i>Unit</i> 10^3/uL	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Id 7</b> <b>entifier:</b> <b>Test::</b> Leukocytes_ PX7	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Result::</b> 4.42	
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b> <i>Low</i>	
			3.9	
			<i>High</i>	
			12.7	
			<i>Unit</i>	
			10 <sup>3</sup> /uL	

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen, Verified**Site No:** 1235**Site Name:** (1235) LSU Health Shreveport**Subject No:** 12351071**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

**5.e Test:**

Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Leukocytes_PX7	Initial Entry

**5.e Result:**

Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4.42	Initial Entry

**5.e LNMT**

Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 3.9  <i>High</i> 12.7  <i>Unit</i> 10 <sup>3</sup> /uL	Initial Entry

**5.f**

Date	Location	User	Value	Reason
Oct-05-2020 09:31:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined</b> 608 <b>Identifier:</b> <b>Test::</b> Neutrophils_ PX608	Changed Information

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen, Verified**Site No:** 1235**Site Name:** (1235) LSU Health Shreveport**Subject No:** 12351071**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Result::</b> 1.3 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 1.8  <i>High</i> 7.7  <i>Unit</i> 10 <sup>3</sup> /uL	
Oct-05-2020 09:30:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 608 <b>Test::</b> Neutrophils_PX608 <b>Result::</b> 1.3 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 38  <i>High</i> 73  <i>Unit</i> %	Changed Information
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 608 <b>Test::</b> Neutrophils_PX608 <b>Result::</b> 29.9 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 38  <i>High</i> 73  <i>Unit</i> %	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.f Sponsor ID:

Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 608	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Neutrophils_PX608	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Oct-05-2020 09:30:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1.3	Changed Information
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 29.9	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Oct-05-2020 09:31:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Low 1.8  High 7.7  Unit 10 <sup>3</sup> /uL	Changed Information
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Low 38  High 73	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

			Unit %	
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5.g

Date	Location	User	Value	Reason
Oct-05-2020 09:31:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 609 <b>Test::</b> Eosinophils_PX609 <b>Result::</b> 0.1 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0.0 <i>High</i> 0.5 <i>Unit</i> 10 <sup>3</sup> /uL	Changed Information
Oct-05-2020 09:31:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 609 <b>Test::</b> Eosinophils_PX609 <b>Result::</b> 0.1 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0 <i>High</i> 8.0 <i>Unit</i> %	Changed Information
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 609	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Test::</b> Eosinophils_ PX609	
			<b>Result::</b> 2.7	
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b> <i>Low</i> 0	
			<i>High</i> 8.0	
			<i>Unit</i> %	

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History  
on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

**5.g Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 609	Initial Entry

**5.g Test:**

Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Eosinophils_PX609	Initial Entry

**5.g Result:**

Date	Location	User	Value	Reason
Oct-05-2020 09:31:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0.1	Changed Information
Oct-03-2020 12:09:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Queried at Logline #03
Oct-02-2020 15:47:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Ranges and values entered in percentages.
Sep-30-2020 04:50:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4845385;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Site No: 1235

Site Name: (1235) LSU Health Shreveport

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

				appropriate.
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2.7	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Oct-05-2020 09:31:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0.0  <i>High</i> 0.5  <i>Unit</i> 10 <sup>3</sup> /uL	Changed Information
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0  <i>High</i> 8.0  <i>Unit</i> %	Initial Entry

5.h

Date	Location	User	Value	Reason
Oct-05-2020 09:32:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Monocytes_PX612 <b>Result::</b> 0.6 <b>Not Done::</b>	Changed Information

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Lab Normal Range:</b> <i>Low</i> 0.3  <i>High</i> 1.0  <i>Unit</i> 10 <sup>3</sup> /uL	
Oct-05-2020 09:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Monocytes_ PX612 <b>Result::</b> 0.6 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 4.0  <i>High</i> 15.0  <i>Unit</i> %	Changed Information

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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5.h				
Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 612 <b>Test::</b> Monocytes_P X612 <b>Result::</b> 14.0 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 4.0  <i>High</i> 15.0  <i>Unit</i> %	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

**5.h Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 612	Initial Entry

**5.h Test:**

Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Monocytes_PX612	Initial Entry

**5.h Result:**

Date	Location	User	Value	Reason
Oct-05-2020 09:32:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0.6	Changed Information
Oct-03-2020 12:09:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Queried at Logline #03
Oct-02-2020 15:48:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Ranges and values entered in percentages.
Sep-30-2020 05:24:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4845402;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

				appropriate.
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 14.0	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Oct-05-2020 09:32:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0.3  <i>High</i> 1.0  <i>Unit</i> 10 <sup>3</sup> /uL	Changed Information
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 4.0  <i>High</i> 15.0  <i>Unit</i> %	Initial Entry

5.i

Date	Location	User	Value	Reason
Oct-05-2020 09:33:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined I 610 identifier:</b> <b>Test::</b> Basophils_P X610 <b>Result::</b> 0.02 <b>Not Done::</b>	Changed Information

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

			<b>Lab Normal Range:</b> <i>Low</i> 0.0  <i>High</i> 0.20  <i>Unit</i> 10 <sup>3</sup> /uL	
Oct-05-2020 09:33:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 610 <b>Test::</b> Basophils_P X610 <b>Result::</b> 0.02 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0.0  <i>High</i> 1.9  <i>Unit</i> %	Changed Information
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 610 <b>Test::</b> Basophils_P X610 <b>Result::</b> 0.5 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0.0  <i>High</i> 1.9  <i>Unit</i> %	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

**5.i Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 610	Initial Entry

**5.i Test:**

Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Basophils_PX610	Initial Entry

**5.i Result:**

Date	Location	User	Value	Reason
Oct-05-2020 09:33:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 0.02	Changed Information
Oct-03-2020 12:09:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Queried at Logline #03
Oct-02-2020 15:48:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Ranges and values entered in percentages.
Sep-30-2020 05:39:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4845433;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

				appropriate.
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> : 0.5	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Oct-05-2020 09:33:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0.0  <i>High</i> 0.20  <i>Unit</i> 10 <sup>3</sup> /uL	Changed Information
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0.0  <i>High</i> 1.9  <i>Unit</i> %	Initial Entry

5.j

Date	Location	User	Value	Reason
Oct-05-2020 09:34:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined 611 Identifier:</b> <b>Test::</b> Lymphocytes _PX611 <b>Result::</b> 2.3 <b>Not Done::</b>	Changed Information

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

			<b>Lab Normal Range:</b> <i>Low</i> 1.0  <i>High</i> 4.8  <i>Unit</i> 10 <sup>3</sup> /uL	
Oct-05-2020 09:33:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 611 <b>Test::</b> Lymphocytes_PX611 <b>Result::</b> 2.3 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 18.0  <i>High</i> 48.0  <i>Unit</i> %	Changed Information
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 611 <b>Test::</b> Lymphocytes_PX611 <b>Result::</b> 52.9 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 18.0  <i>High</i> 48.0  <i>Unit</i> %	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

**5.j Sponsor ID:**

Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 611	Initial Entry

**5.j Test:**

Date	Location	User	Value	Reason
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Lymphocytes_PX611	Initial Entry

**5.j Result:**

Date	Location	User	Value	Reason
Oct-05-2020 09:33:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2.3	Changed Information
Oct-03-2020 12:11:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Queried at Logline #03
Oct-02-2020 15:48:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Ranges and values entered in percentages.
Sep-30-2020 05:42:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW4845430;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

				appropriate.
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 52.9	Initial Entry

**5.j LNMT**

Date	Location	User	Value	Reason
Oct-05-2020 09:34:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 1.0  <i>High</i> 4.8  <i>Unit</i> 10 <sup>3</sup> /uL	Changed Information
Sep-29-2020 10:28:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 18.0  <i>High</i> 48.0  <i>Unit</i> %	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail  
on Sep/22/2020

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

**Form Status:**

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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

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Date	Location	User	Value	Reason
Oct-16-2020 09:13:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	response to query

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History  
on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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

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**1. Date:**

Date	Location	User	Value	Reason
Oct-16-2020 11:56:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Katherine Puig (b) (4)	Query 1: Closed	Response satisfies query
Oct-15-2020 22:14:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 1: Opened	If no entries for row #1, please delete the row by clicking on row and selecting the DELETE option.

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail  
on Sep/22/2020

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

**Form Status:**

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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Date	Location	User	Value	Reason
Sep-29-2020 11:12:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail  
on Sep/22/2020

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

**Form Status:**

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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Date	Location	User	Value	Reason
Sep-29-2020 11:13:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail  
on Sep/22/2020

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

**Form Status:**

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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Date	Location	User	Value	Reason
Sep-29-2020 11:17:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail  
on Sep/22/2020

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

**Form Status:**

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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Date	Location	User	Value	Reason
Sep-29-2020 11:19:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail  
on Sep/22/2020

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

**Form Status:**

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 19:09

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Date	Location	User	Value	Reason
Sep-29-2020 11:21:00 (UTC-06:00) Central 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 Sep/22/2020

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

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**1. Date:**

Date	Location	User	Value	Reason
Sep-29-2020 11:12:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/26/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-29-2020 11:12:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Systolic::</b> 11 8 <b>Diastolic::</b> 79 <b>Respiratory Rate in respirat</b> 16 <b>ions/minute:</b> <b>Heart Rate in beats/minute:</b> 80	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-29-2020 11:12:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Systolic:**

Date	Location	User	Value	Reason
Sep-29-2020 11:12:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 118	Initial Entry

**2.a Diastolic:**

Date	Location	User	Value	Reason
Sep-29-2020 11:12:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 79	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History  
on Sep/22/2020

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

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

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**2.a Respiratory Rate in respirations/minute:**

Date	Location	User	Value	Reason
Sep-29-2020 11:12:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 16	Initial Entry

**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Sep-29-2020 11:12:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 80	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Sep/22/2020

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

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**1. Date:**

Date	Location	User	Value	Reason
Sep-29-2020 11:13:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/25/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-29-2020 11:13:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Systolic::</b> 18 2 <b>Diastolic::</b> 72 <b>Respiratory Rate in respirat</b> 15 <b>ions/minute:</b> <b>Heart Rate in beats/minute:</b> 90	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-29-2020 11:13:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Systolic:**

Date	Location	User	Value	Reason
Oct-02-2020 10:17:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-01-2020 13:41:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Not clinically significant per PI
Sep-30-2020 07:39:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Thank you for response. Please review the value

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Sep/22/2020

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

				and confirm if it is clinically significant or not.
Sep-29-2020 11:14:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Sep-29-2020 11:13:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 182 is outside of Normal Range 90 - 140.
Sep-29-2020 11:13:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 182	Initial Entry

**2.a Diastolic:**

Date	Location	User	Value	Reason
Sep-29-2020 11:13:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 72	Initial Entry

**2.a Respiratory Rate in respirations/minute:**

Date	Location	User	Value	Reason
Sep-29-2020 11:13:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 15	Initial Entry

**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Sep-29-2020 11:13:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 90	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History  
on Sep/22/2020

**Form Version:** 15-Sep-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Date:**

Date	Location	User	Value	Reason
Sep-29-2020 11:17:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/24/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-29-2020 11:17:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Systolic::</b> 12 0 <b>Diastolic::</b> 80 <b>Respiratory Rate in respirat</b> 20 <b>ions/minute:</b> <b>Heart Rate in beats/minute:</b> 83	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-29-2020 11:17:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Systolic:**

Date	Location	User	Value	Reason
Sep-29-2020 11:17:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 120	Initial Entry

**2.a Diastolic:**

Date	Location	User	Value	Reason
Sep-29-2020 11:17:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 80	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History  
on Sep/22/2020

**Form Version:** 15-Sep-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**2.a Respiratory Rate in respirations/minute:**

Date	Location	User	Value	Reason
Sep-29-2020 11:17:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 20	Initial Entry

**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Sep-29-2020 11:17:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 83	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History  
on Sep/22/2020

**Form Version:** 15-Sep-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Date:**

Date	Location	User	Value	Reason
Sep-29-2020 11:19:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/23/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-29-2020 11:19:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Systolic::</b> 14 5 <b>Diastolic::</b> 94 <b>Respiratory Rate in respirat</b> 11 <b>ions/minute:</b> <b>Heart Rate in beats/minute:</b> 70	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-29-2020 11:19:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Systolic:**

Date	Location	User	Value	Reason
Oct-02-2020 10:17:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-01-2020 13:41:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Not clinically significant per PI
Sep-30-2020 07:39:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Thank you for response. Please review the value

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Sep/22/2020

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

				and confirm if it is clinically significant or not.
Sep-29-2020 11:19:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Sep-29-2020 11:19:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 145 is outside of Normal Range 90 - 140.
Sep-29-2020 11:19:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 145	Initial Entry

**2.a Diastolic:**

Date	Location	User	Value	Reason
Oct-02-2020 10:17:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-01-2020 13:42:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Not clinically significant per PI
Sep-30-2020 07:40:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Thank you for response. Please review the value and confirm if it is clinically significant or not.
Sep-29-2020 11:19:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Sep-29-2020 11:19:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Diastolic BP 94 is outside of Normal Range 60 - 90.
Sep-29-2020 11:19:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 94	Initial Entry

**2.a Respiratory Rate in respirations/minute:**

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History  
on Sep/22/2020

**Form Version:** 15-Sep-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

Date	Location	User	Value	Reason
Sep-29-2020 11:19:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 11	Initial Entry

*2.a Heart Rate in beats/minute:*

Date	Location	User	Value	Reason
Sep-29-2020 11:19:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 70	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History  
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**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

**Generated By:** (b) (4)

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**1. Date:**

Date	Location	User	Value	Reason
Sep-29-2020 11:21:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/22/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-29-2020 11:21:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Systolic::</b> 13 1 <b>Diastolic::</b> 95 <b>Respiratory Rate in respirat</b> 26 <b>ions/minute:</b> <b>Heart Rate in beats/minute:</b> 11 1	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-29-2020 11:21:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Systolic:**

Date	Location	User	Value	Reason
Sep-29-2020 11:21:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 131	Initial Entry

**2.a Diastolic:**

Date	Location	User	Value	Reason
Oct-02-2020 10:15:24 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History  
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**Form Version:** 15-Sep-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

Time (US & Canada)		(b) (4), (b) (6)		
Oct-01-2020 13:43:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Not clinically significant per PI
Sep-30-2020 07:40:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Thank you for response. Please review the value and confirm if it is clinically significant or not.
Sep-29-2020 11:21:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Sep-29-2020 11:21:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Diastolic BP 95 is outside of Normal Range 60 - 90.
Sep-29-2020 11:21:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 95	Initial Entry

**2.a Respiratory Rate in respirations/minute:**

Date	Location	User	Value	Reason
Sep-29-2020 11:21:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 26	Initial Entry

**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Sep-29-2020 11:21:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 111	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail on Sep/22/2020

**Form Version:** 21-Aug-2020 02:51

**Form Status:**

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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Date	Location	User	Value	Reason
Sep-29-2020 11:24:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 **Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Date:**

Date	Location	User	Value	Reason
Sep-29-2020 11:24:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/23/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-29-2020 11:24:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Oxygen Saturation:</b> 95.0	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-29-2020 11:24:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a SPO2 Pulse Oximetry %**

Date	Location	User	Value	Reason
Sep-29-2020 11:24:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 95.0	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail  
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**Form Version:** 15-Sep-2020 21:54

**Form Status:**

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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Date	Location	User	Value	Reason
Oct-13-2020 10:57:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	query resolution
Oct-13-2020 10:56:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Undeleted	attempting to fix query
Oct-12-2020 11:12:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	per query
Sep-29-2020 11:21:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail  
on Sep/22/2020

**Form Version:** 15-Sep-2020 21:54

**Form Status:**

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

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**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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Date	Location	User	Value	Reason
Sep-29-2020 11:23:00 (UTC-06:00) Central 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 - Audit Trail  
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**Form Version:** 15-Sep-2020 21:54

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**Site Name:** (1235) LSU Health Shreveport

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**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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Date	Location	User	Value	Reason
Sep-29-2020 11:25:22 (UTC-06:00) Central 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 - Audit Trail  
on Sep/22/2020

**Form Version:** 15-Sep-2020 21:54

**Form Status:**

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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Date	Location	User	Value	Reason
Sep-29-2020 11:26:09 (UTC-06:00) Central 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 - Audit Trail  
on Sep/22/2020

**Form Version:** 15-Sep-2020 21:54

**Form Status:**

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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Date	Location	User	Value	Reason
Sep-29-2020 11:27:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

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1. Date:

Date	Location	User	Value	Reason
Oct-14-2020 21:19:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 1: Closed	Response satisfies query
Oct-13-2020 10:58:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry
Oct-11-2020 08:55:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Saumitra Dubey (b) (4)	Query 1: Reissued:Opened	Thanks for removing the data, kindly delete the log if no data to enter.
Oct-09-2020 08:03:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-09-2020 08:03:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Changed Information
Oct-08-2020 20:49:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 1: Opened	*DM: There are 2 values for O2 Saturation reported for 23/Sep/20. Per CRF guidelines, please report the lowest value for the date and any duplicate entry for the date.
Sep-29-2020 11:21:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/23/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
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090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

Oct-13-2020 10:58:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 : <b>Oxygen Saturation:</b> Not Applicable	Initial Entry
Oct-09-2020 08:02:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 <b>Oxygen Saturation:</b>	changed per query
Sep-29-2020 11:21:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 <b>Oxygen Saturation:</b> 96.0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-29-2020 11:21:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Oct-13-2020 10:58:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Oct-09-2020 08:02:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	changed per query
Sep-29-2020 11:21:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 96.0	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Sep/22/2020**Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail  
History**Form Version:** 15-Sep-2020 21:54**Form Status:** Data Complete, Frozen, Verified**Site No:** 1235**Site Name:** (1235) LSU Health Shreveport**Subject No:** 12351071**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Sep-29-2020 11:23:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-29-2020 11:23:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/22/2020	Transcription Error
Sep-29-2020 11:23:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date is before Date of First Symptom Started on the Signs and Symptoms form in the same visit. Please review and update as appropriate.
Sep-29-2020 11:23:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/22/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-29-2020 11:23:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Oxygen Saturation:</b> 96.0	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-29-2020 11:23:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a SPO2 Pulse Oximetry %**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 **Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

Sep-29-2020 11:23:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 96.0	Initial Entry
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Date:**

Date	Location	User	Value	Reason
Sep-29-2020 11:25:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/24/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-29-2020 11:25:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Oxygen Saturation:</b> 93.0	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-29-2020 11:25:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a SPO2 Pulse Oximetry %**

Date	Location	User	Value	Reason
Sep-29-2020 11:25:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 93.0	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Date:**

Date	Location	User	Value	Reason
Sep-29-2020 11:26:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/25/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-29-2020 11:26:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Oxygen Saturation:</b> 97.0	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-29-2020 11:26:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a SPO2 Pulse Oximetry %**

Date	Location	User	Value	Reason
Sep-29-2020 11:26:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 97.0	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Date:**

Date	Location	User	Value	Reason
Sep-29-2020 11:27:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/26/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-29-2020 11:27:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Oxygen Saturation:</b> 96.0	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-29-2020 11:27:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a SPO2 Pulse Oximetry %**

Date	Location	User	Value	Reason
Sep-29-2020 11:27:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 96.0	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History on Sep/22/2020

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Date Time of Assessment:**

Date	Location	User	Value	Reason
Oct-27-2020 12:47:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Arterial Blood Gases PaO2 (mmHg):**

Date	Location	User	Value	Reason
Oct-27-2020 12:47:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. FiO2 (Fraction of Inhaled Oxygen):**

Date	Location	User	Value	Reason
Oct-27-2020 12:47:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Oct-27-2020 12:48:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Oct-27-2020 12:48:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Oct-27-2020 12:48:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Medication:**

*Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).*

Date	Location	User	Value	Reason
Oct-27-2020 12:48:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Oct-27-2020 12:48:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Ongoing?**

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

Date	Location	User	Value	Reason
Oct-27-2020 12:48:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** IMAGING - Audit Trail  
on Sep/22/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:**

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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Date	Location	User	Value	Reason
Sep-29-2020 11:29:27 (UTC-06:00) Central 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 Sep/22/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Sep-29-2020 11:29:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/22/2020	Initial Entry

**2. Location of Assessment:**

Date	Location	User	Value	Reason
Sep-29-2020 11:29:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHEST	Initial Entry

**3. Type of Imaging Exam:**

Date	Location	User	Value	Reason
Sep-29-2020 11:29:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> X-RAY	Initial Entry

**4. Assessment:**

Date	Location	User	Value	Reason
Sep-29-2020 11:29:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ABNORMAL <i>If abnormal, specify findings:</i>  Minimal bibasilar infiltrates	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Oct/22/2020

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit  
Trail History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Date of Visit**

Date	Location	User	Value	Reason
Oct-22-2020 15:52:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/22/2020	Initial Entry

**3. COVID-19 Illness Visit:**

Date	Location	User	Value	Reason
Oct-22-2020 15:52:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COVID_A1	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Oct/22/2020

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1235

**Subject No:** 12351071

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-22-2020 15:55:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-22-2020 15:55:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-22-2020 16:12:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-22-2020 15:55:54 (UTC-06:00) Central 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-22-2020 15:55:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/22/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-22-2020 16:12:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BLD43G	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Oct/22/2020

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-22-2020 16:12:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BLD43G	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Oct-22-2020 16:12:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BLD43F	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Oct-22-2020 16:12:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BLD43F	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Oct-22-2020 16:12:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP1DR4	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Oct-22-2020 16:12:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP1DR4	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Oct-12-2020 15:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/22/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-12-2020 15:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-12-2020 15:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO LONGER MEETS ELIGIBIL ITY CRITERIA	Initial Entry

**4. Specify Status:**

Date	Location	User	Value	Reason
Dec-01-2020 04:54:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Nov-30-2020 15:14:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	per query
Nov-30-2020 15:14:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclusion Criteria 5	per query
Nov-30-2020 12:54:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	CLINQUERY: Please capture in this field the eligibility criterion number not met/met (eg Exclusion criterion

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

				#) to match to the status selection NO LONGER MEETS ELIGIBILITY CRITERIA
Oct-12-2020 15:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Will continue follow up, but will not receive vaccine 2.	Initial Entry

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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*1. Date of Visit*

Date	Location	User	Value	Reason
Dec-18-2020 13:33:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/16/2020	Initial Entry



**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form Version:** 10-Dec-2020 02:25

**Site No:** 1235

**Subject No:** 12351071

**Generated By:** (b) (4)

**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit  
Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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*1. Select appropriate response - Is participant willing to return for Vaccination 3?*

Date	Location	User	Value	Reason
Dec-18-2020 13:34:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-18-2020 13:34:11 (UTC-06:00) Central 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-18-2020 13:34:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1235

**Subject No:** 12351071

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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*1. Date of Visit*

Date	Location	User	Value	Reason
Dec-18-2020 13:37:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/18/2020	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:31

**Site No:** 1235

**Subject No:** 12351071

**Generated By:** (b) (4)

**Form:** INFORMED CONSENT - FURTHER VACCINATION - eCRF  
Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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*I. Consent Was:*

Date	Location	User	Value	Reason
Dec-18-2020 13:37:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Dec/18/2020	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:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Dec-18-2020 13:39:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/18/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Dec-18-2020 13:39:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Dec-18-2020 13:39:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (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: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Dec-18-2020 13:39:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-18-2020 13:39:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-18-2020 14:00:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-18-2020 13:39:23 (UTC-06:00) Central 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-18-2020 13:39:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Dec/18/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-18-2020 14:00:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP0Y20	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (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: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

5.a Sample ID

Date	Location	User	Value	Reason
Dec-18-2020 14:00:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP0Y20	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-18-2020 14:00:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRV43K	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-18-2020 14:00:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRV43K	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-18-2020 14:01:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRV43M	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-18-2020 14:01:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRV43M	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (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: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Dec-18-2020 13:39:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-18-2020 13:39:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-18-2020 14:01:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-18-2020 13:39:50 (UTC-06:00) Central 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-18-2020 13:39:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Dec/18/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-18-2020 14:01:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP0Y1D	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (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:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**5.a Sample ID**

Date	Location	User	Value	Reason
Dec-18-2020 14:01:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP0Y1D	Initial Entry



Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1235

Subject No: 12351071

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1235) LSU Health Shreveport

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 19:09

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Dec-18-2020 13:40:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Dec-18-2020 13:40:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Dec-18-2020 13:40:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Dec-18-2020 13:40:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/18/2020 09:48	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Dec-18-2020 13:40:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Dec-18-2020 13:40:50 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

Time (US & Canada)	(b) (4), (b) (6)
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**7. Route:**

Date	Location	User	Value	Reason
Dec-18-2020 13:40:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**8. Actual Dose:**

Date	Location	User	Value	Reason
Dec-18-2020 13:40:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Dec-18-2020 13:40:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Dec-18-2020 13:40:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

**11. Was the subject observed for at least the protocol specified observation period after investigational product administration?**

Date	Location	User	Value	Reason
Dec-18-2020 13:40:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1235

**Subject No:** 12351071

**Generated By:** (b) (4)

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Dec-18-2020 13:34:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/16/2020	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Dec-18-2020 13:34:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1235

**Subject No:** 12351071

**Generated By:** (b) (4)

**Form:** WITHDRAWAL OF CONSENT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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***1. Withdrawal of Consent Date :***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Dec-18-2020 13:35:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1235

**Subject No:** 12351071

**Generated By:** (b) (4)

**Form:** DEATH DETAILS CODED - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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*1. Date of Collection / Notification of Death:*

Date	Location	User	Value	Reason
Dec-18-2020 13:35:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1235

**Subject No:** 12351071

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-08-2021 17:44:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/8/2021	Initial Entry

Header Text: c4591001

Visit: V102\_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1235

Site Name: (1235) LSU Health Shreveport

Subject No: 12351071

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 19:09

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-08-2021 17:02:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-08-2021 17:02:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-08-2021 17:02:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-08-2021 17:02:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-08-2021 17:02:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/8/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-08-2021 17:02:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP0Y6B	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (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:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-08-2021 17:02:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP0Y6B	Initial Entry



Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1235

Subject No: 12351071

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1235) LSU Health Shreveport

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 19:09

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Jan-08-2021 17:45:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Jan-08-2021 17:45:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Jan-08-2021 17:45:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Jan-08-2021 17:45:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/8/2021 10:46	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Jan-08-2021 17:45:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Jan-08-2021 17:45:39 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1235

Subject No: 12351071

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1235) LSU Health Shreveport

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 19:09

Time (US & Canada)

7. Route:

Date	Location	User	Value	Reason
Jan-08-2021 17:45:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-08-2021 17:45:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-08-2021 17:45:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-08-2021 17:45:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Jan-08-2021 17:45:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1235

**Subject No:** 12351071

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-05-2021 10:01:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V103\_MONTH1

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1235

**Subject No:** 12351071

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Contact Type:**

Date	Location	User	Value	Reason
Feb-05-2021 10:01:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> TELEPHONE VISIT	Initial Entry

**2. Was contact made?**

Date	Location	User	Value	Reason
Feb-05-2021 10:01:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Contact:  Feb/5/2021	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (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:** 1235**Site Name:** (1235) LSU Health Shreveport**Subject No:** 12351071**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 19:09[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Feb-08-2021 05:29:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clos ed	Incorrect query
Feb-05-2021 14:55:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Ope ned	DMW7169115;Status on the Disposition - Treatment form is COMPLETED, but Date is different than Visit 3 Date. Please review and update as appropriate.
Feb-05-2021 10:02:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/5/ 2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Feb-05-2021 10:02:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> OPEN LABEL TREATMENT	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Feb-05-2021 10:02:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1235

**Subject No:** 12351071

**Generated By:** (b) (4)

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1235) LSU Health Shreveport

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 19:09

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**1. Subject Status**

Date	Location	User	Value	Reason
Oct-12-2020 15:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Initial Entry
Sep-14-2020 09:42:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Sep-14-2020 09:40:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Oct-12-2020 15:10:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/22/2020	Initial Entry
Sep-14-2020 09:42:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/14/2020	Initial Entry
Sep-14-2020 09:40:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/14/2020	Initial Entry

090177e196ae3034\Final\Final On: 01-Apr-2021 04:03 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Verified

**Site No:** 1235

**Site Name:** (1235) LSU Health Shreveport

**Subject No:** 12351071

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 19:09

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*1. Casebook Signature*

Date	Location	User	Value	Reason
Oct-16-2020 10:28:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry