

**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:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

[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:** 1088

**Subject No:** 10881126

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

**Form:** MAIN INFORMED CONSENT

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/31/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** DEMOGRAPHY

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10881126]
2.	Birth Date:	(b) (6)/1954
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:	

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** DATE OF VISIT

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Aug/31/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

**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:** 1088

**Subject No:** 10881126

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation/Death	Aug/31/2020
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: 1088

Subject No: 10881126

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1088) PMG Research of Hickory LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

eCRF Audit Trail History

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hypertension]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[hypercholesterolemia]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[heart burn - intermittent]
	Start Date:	UNK/UNK/2012
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Coronary Artery Disease (CAD)]
	Start Date:	UNK/UNK/1983
	Ongoing:	YES

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Obesity]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES



**Header Text:** c4591001

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

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

**eCRF Audit Trail History**

**Vital Signs**

1.	Date:	Aug/31/2020
2.	Weight:	[143.6]
3.	Unit:	kg
4.	Height:	[187.9]
5.	Unit:	cm
6.	Body Mass Index:	[40.7]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[97.9]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** RANDOMIZATION

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Aug/31/2020
2.	Randomization Number:	[246490]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/31/2020
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	[BP96ZW]
5.b	Sample ID	[BP96ZX]
5.c	Sample ID	[BP96ZY]
5.d	Sample ID	[BL9SV8]
5.e	Sample ID	[BL9SV9]

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1088

**Subject No:** 10881126

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

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

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/31/2020
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	[BP97BN]
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090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

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

**Form:** VACCINATION

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

**eCRF Audit Trail History**

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/31/2020 14:28
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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**Header Text:** c4591001

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

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[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:** 1088

**Subject No:** 10881126

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

**Form:** DATE OF VISIT

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/23/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/23/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[97.1]
	Unit:	F
	Temperature Location:	FOREHEAD



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1088

**Subject No:** 10881126

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

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

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/23/2020
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	[BP977H]
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090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** VACCINATION

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

**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/23/2020 08:48
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** DATE OF VISIT

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/26/2020
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, Locked, Frozen, Verified

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/26/2020
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	[BR96X9]
5.b	Sample ID	[BR96XB]
5.c	Sample ID	[BR96XC]
5.d	Sample ID	[BRZF62]
5.e	Sample ID	[BRZF63]

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

**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:** V5\_MONTH12\_L

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

**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:** V6\_MONTH24\_L

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

**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:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET  
on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Date of Visit**

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

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

**eCRF Audit Trail History**

**Signs and Symptoms**

1.	Date of Assessment:	Nov/30/2020
2.	Date of First Symptom Started:	Nov/29/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Dec/1/2020

**Symptoms**

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

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

4.i	Symptoms:	VOMITING
	Was symptom present?	NO

**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:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN  
on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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

- [Back to Form](#)
- [Form Comments](#)
- [eCRF Audit Trail History](#)
- [Form Audit Trail](#)

**Microbiology Specimen**

1.	Actual Date of Collection:	//	<a href="#">Comments</a>
2.	Specimen Type:		<a href="#">Comments</a>
3.	Specimen Collection Location:		<a href="#">Comments</a>
4.	Assay Code and Description:		<a href="#">Comments</a>
5.	Device Type:		<a href="#">Comments</a>
6.	Trade Name:		<a href="#">Comments</a>
7.	Test Result:		<a href="#">Comments</a>
8.	Comments/Findings/Details:	[ ]	<a href="#">Comments</a>
9.	Trade Name Other, Specify:	[ ]	<a href="#">Comments</a>

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN  
on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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**Microbiology Specimen**

1.	Actual Date of Collection:	Dec/1/2020
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:	QUIDEL CORPORATION LYRA SARS-COV-2 ASSAY
7.	Test Result:	POSITIVE
8.	Comments/Findings/Details:	[ ]
9.	Trade Name Other, Specify:	[ ]

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[CV22684]
-----	-----------	-----------

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

[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:	[self swab 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 Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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**Health Care Utilization**

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

**Health Care Utilization Other**

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

**Health Care Utilization**

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

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**Header Text:** c4591001

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

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT  
on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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**Respiratory Treatment**

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS  
on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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**Illness Details**

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [COVID-19]  Date of Diagnosis: Dec/1/2020
3.	Toxicity Grade:	5

**Header Text:** c4591001

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

**Form:** ILLNESS DETAILS - SEVERE

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE  
on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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**Illness Details**

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



Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

#	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	

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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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>

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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>

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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: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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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 _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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.c	Sponsor ID:	Not Done _____ [ ]	<a href="#">Comments</a>
	Test:	Erythrocytes_PX3	
	Result:	Not Done _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Done _____	<a href="#">Comments</a>
	LNMT	Not Done _____ 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 Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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:	Leukocytes_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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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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>

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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>

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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>

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

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

**Form:** VITAL SIGNS - COVID

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID  
on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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**Vital Signs**

1.	Date:	Not Done _____ //	<a href="#">Comments</a>
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**Vital Signs Details**

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

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

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

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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**Vital Signs**

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

**Vital Signs Details**

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

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)



**Header Text:** c4591001

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

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS  
on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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**Oxygenation Parameters**

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

**Header Text:** c4591001

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

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS  
on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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**Concomitant Medications**

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

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

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

**Form:** IMAGING

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** IMAGING  
on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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**Imaging**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA - New  
Unscheduled Visit

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

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

**Form Status:** Not Started

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA - New  
Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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



**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

**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:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

**Unplanned Assessments**

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

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation/Death :	Oct/26/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** DISPOSITION - FOLLOW-UP

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

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**Disposition - Follow-Up**

1.	Date of Completion/Discontinuation/Death :	Dec/1/2020
2.	Phase of Disposition:	FOLLOW-UP
3.	Status:	DEATH
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:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

**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:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	cardiac arrest	Dec/1/2020 UNK: UNK	NO End Date Time:  Dec/1/2020 UNK:UNK	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	COVID-19	Nov/29/2020 UNK: :UNK	NO End Date Time:  Dec/1/2020 04:00	<a href="#">Repeating Pages</a>
3.	ADVERSE EVENT	3	Coronary Artery Disease	Dec/1/2020 UNK: UNK	NO End Date Time:  Dec/1/2020 16:00	<a href="#">Repeating Pages</a>

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

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**Adverse Event Report**

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

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	FATAL
14.	Did the adverse event cause the subject to be discontinued from the study?	YES
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021117426]

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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1088**Subject No:** 10881126**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1088) PMG Research of Hickory LLC**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:22

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[COVID-19]
4.	Start Date Time:	Nov/29/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/1/2020 04:00
6.	Toxicity Grade:	4
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? YES  Did this serious event require or prolong hospitalization? NO  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? YES  Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [COVID-19]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	FATAL
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021117426]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1088

Subject No: 10881126

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Queries, Verified

Site Name: (1088) PMG Research of Hickory LLC

Subject Initials: ---

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Coronary Artery Disease]
4.	Start Date Time:	Dec/1/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/1/2020 16:00
6.	Toxicity Grade:	4
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? YES  Did this serious event require or prolong hospitalization? NO  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? YES  Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [cardiac arrest]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	FATAL
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021117426]

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**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

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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:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

#	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:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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**Concomitant Medications**

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

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**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

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**Concomitant Medications**

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

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**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

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**Radiation Treatment**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

#	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:** 1088

**Subject No:** 10881126

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

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[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:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

**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:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

**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:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

**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?	

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (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:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

**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:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form Version:** 14-Jan-2021 02:29

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** INFORMED CONSENT - ASYMPTOMATIC  
SURVEILLANCE

**Form Status:** Not Started

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

**Informed Consent - Asymptomatic Surveillance**

1.	Consent Was:	
----	--------------	--

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

**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	[ ]
----	-----------	-----

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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



**Header Text:** c4591001

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

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

**Date of Visit**

1.	Date of Visit	//
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:** Not Started

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

**Further Vaccination Confirmation**

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	
----	---	--

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** TREATMENT UNBLINDED

**Form Status:** Not Started

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

**Treatment Unblinded**

1.	Date Treatment Unblinded :	//
2.	Primary Reason for Unblinding:	

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

**Withdrawal Of Consent**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** DEATH DETAILS CODED

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Death Details**

1.	Date of Collection / Notification of Death:	Dec/1/2020
----	---	------------

**Cause of Death**

2.a	Cause of Death Status:	PRIMARY CAUSE OF DEATH
	Cause of Death:	[Cardiac arrest]
2.b	Cause of Death Status:	SECONDARY CAUSE OF DEATH
	Cause of Death:	[COVID-19]

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Dec/1/2020

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

[eCRF Audit Trail History](#)

**Casebook Signature Form**

1.	Casebook Signature	Click Here to Enable
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090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
(b) (6)	Approved	Mar-05-2021 10:40:04 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, (b) (6) verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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



**Header Text:** c4591001

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

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

**Site No:** 1088

**Subject No:** 10881126

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

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

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

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Item	Date	User	Comment
Form	Aug-31-2020 17:42:32 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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

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Item	Date	User	Comment
Form	Dec-01-2020 13:20:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	
Form	Dec-01-2020 12:47:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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

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Item	Date	User	Comment
1	Dec-01-2020 13:20:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	
1	Dec-01-2020 12:47:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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

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Item	Date	User	Comment
2	Dec-01-2020 13:20:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	
2	Dec-01-2020 12:47:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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

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Item	Date	User	Comment
3	Dec-01-2020 13:20:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	
3	Dec-01-2020 12:47:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Done

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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

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Item	Date	User	Comment
4	Dec-01-2020 13:20:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	
4	Dec-01-2020 12:47:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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

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Item	Date	User	Comment
5	Dec-01-2020 13:20:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	
5	Dec-01-2020 12:47:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Done

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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

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Item	Date	User	Comment
6	Dec-01-2020 13:20:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	
6	Dec-01-2020 12:47:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Done



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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

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Item	Date	User	Comment
7	Dec-01-2020 13:20:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	
7	Dec-01-2020 12:47:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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

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Item	Date	User	Comment
8	Dec-01-2020 13:20:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	
8	Dec-01-2020 12:47:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Nov/30/2020

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

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

**Site No:** 1088

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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

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Item	Date	User	Comment
9	Dec-01-2020 13:20:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	
9	Dec-01-2020 12:47:35 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Done

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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Item	Date	User	Comment
Form	Dec-01-2020 12:52:30 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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Item	Date	User	Comment
1	Dec-01-2020 12:52:30 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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Item	Date	User	Comment
2	Dec-01-2020 12:52:30 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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Item	Date	User	Comment
3	Dec-01-2020 12:52:30 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

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

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

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Item	Date	User	Comment
Form	Dec-01-2020 12:54:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments  
on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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Item	Date	User	Comment
1	Dec-01-2020 12:54:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments  
on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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Item	Date	User	Comment
2	Dec-01-2020 12:54:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments  
on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

[Back to Form](#)

Item	Date	User	Comment
3	Dec-01-2020 12:54:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments  
on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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Item	Date	User	Comment
4	Dec-01-2020 12:54:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
(b) (6)	Approved	Mar-05-2021 10:40:04 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, (b) (6) verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

(b) (6)	N/A	Mar-04-2021 10:35:11 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Mar-03-2021 11:41:09 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, (b) (6) verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

(b) (6)	N/A	Mar-02-2021 12:50:36 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

(b) (6)	Approved	Mar-02-2021 11:48:40 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, (b) (6) verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

(b) (6)	N/A	Mar-01-2021 17:28:21 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Mar-01-2021 16:47:51 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, (b) (6) verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

(b) (6)	N/A	Feb-26-2021 08:48:51 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Feb-26-2021 08:45:11 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)



**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

**Affidavit:**

By my dated signature below, I, (b) (6) verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

(b) (6)	N/A	Feb-23-2021 07:34:53 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Feb-22-2021 14:47:22 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, (b) (6) verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

(b) (6)	N/A	Feb-19-2021 09:47:38 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Feb-16-2021 11:04:07 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001**Visit:** Investigator Signature - Unscheduled**Form:** CASEBOOK SIGNATURE FORM - Signature History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Signed, Verified**Site No:** 1088**Site Name:** (1088) PMG Research of Hickory LLC**Subject No:** 10881126**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:22**Affidavit:**

By my dated signature below, I, (b) (6) 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) (b) (6)	N/A	Feb-15-2021 03:03:14 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Feb-12-2021 11:13:35 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, (b) (6) verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

(b) (6)	N/A	Feb-11-2021 09:47:56 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Dec-14-2020 11:52:02 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Header Text:** c4591001**Visit:** Investigator Signature - Unscheduled**Form:** CASEBOOK SIGNATURE FORM - Signature History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Signed, Verified**Site No:** 1088**Site Name:** (1088) PMG Research of Hickory LLC**Subject No:** 10881126**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:22**Affidavit:**

By my dated signature below, I, (b) (6) 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-11-2020 14:10:50 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Dec-02-2020 10:59:46 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, (b) (6) 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-01-2020 12:46:55 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

(b) (6)	Approved	Nov-02-2020 11:28:09 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

**Affidavit:**

By my dated signature below, I, (b) (6) verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** COHORT\_SELECTION - eCRF Audit Trail History

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Aug-31-2020 17:41:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 17:41:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

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*I. Consent Was:*

Date	Location	User	Value	Reason
Aug-31-2020 17:42:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Aug/31/2020	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1088

Subject No: 10881126

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1088) PMG Research of Hickory LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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**1. Subject ID**

Date	Location	User	Value	Reason
Aug-31-2020 17:41:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10881126	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-31-2020 17:41:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1954	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-31-2020 17:42:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Aug-31-2020 17:42:10 (UTC-05:00) Eastern 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
Aug-31-2020 17:42:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

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*1. Date of Visit*

Date	Location	User	Value	Reason
Aug-31-2020 17:42:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/31/2020	Initial Entry



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1088

Subject No: 10881126

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1088) PMG Research of Hickory LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

[Back to Form](#)

**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Aug-31-2020 17:42:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/31/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-31-2020 17:42:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Aug-31-2020 17:42:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1088

Subject No: 10881126

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1088) PMG Research of Hickory LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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*I.a*

Date	Location	User	Value	Reason
Aug-31-2020 17:43:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number 1</b> : <b>Medical History T hypertension</b> <b>erm:</b> <b>Start Date:</b> UNK/UNK/2 010 <b>Ongoing:</b> YES	Initial Entry

*I.a Line/MH Number:*

Date	Location	User	Value	Reason
Aug-31-2020 17:43:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 17:43:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> hypertension	Initial Entry

*I.a Start Date:*

Date	Location	User	Value	Reason
Aug-31-2020 17:43:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> UNK/UNK/2010	Initial Entry

*I.a Ongoing:*

Date	Location	User	Value	Reason
Aug-31-2020 17:43:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1088

Subject No: 10881126

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1088) PMG Research of Hickory LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

**I.b**

Date	Location	User	Value	Reason
Aug-31-2020 17:44:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 2 <b>Medical History Term:</b> hypercholesterolemia <b>Start Date:</b> UNK/UNK/2010 <b>Ongoing:</b> YES	Initial Entry

**I.b Line/MH Number:**

Date	Location	User	Value	Reason
Aug-31-2020 17:44:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 17:44:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> hypercholesterolemia	Initial Entry

**I.b Start Date:**

Date	Location	User	Value	Reason
Aug-31-2020 17:44:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2010	Initial Entry

**I.b Ongoing:**

Date	Location	User	Value	Reason
Aug-31-2020 17:44:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.c**

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1088

Subject No: 10881126

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1088) PMG Research of Hickory LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

Date	Location	User	Value	Reason
Aug-31-2020 17:44:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Num</b> 3 <b>ber:</b> <b>Medical History Term:</b> heart burn - intermittent <b>Start Date:</b> UNK/UNK/2012 <b>Ongoing:</b> YES	Initial Entry

*I.c Line/MH Number:*

Date	Location	User	Value	Reason
Aug-31-2020 17:44:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 17:44:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> heart burn - intermittent	Initial Entry

*I.c Start Date:*

Date	Location	User	Value	Reason
Aug-31-2020 17:44:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2012	Initial Entry

*I.c Ongoing:*

Date	Location	User	Value	Reason
Aug-31-2020 17:44:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

*I.d*

Date	Location	User	Value	Reason
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090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

Aug-31-2020 17:45:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 4 <b>Medical History Term:</b> Coronary Artery Disease (CAD) <b>Start Date:</b> UNK/UNK/1983 <b>Ongoing:</b> YES	Initial Entry
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090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1088

Subject No: 10881126

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1088) PMG Research of Hickory LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

***1.d Line/MH Number:***

Date	Location	User	Value	Reason
Aug-31-2020 17:45:45 (UTC-05:00) Eastern 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
Aug-31-2020 17:45:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Coronary Artery Disease (CAD)	Initial Entry

***1.d Start Date:***

Date	Location	User	Value	Reason
Mar-08-2021 07:55:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Closed	Response satisfies query
Mar-08-2021 07:38:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	date is correct per the information given to us by the patient.
Mar-07-2021 05:59:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (b) (4)	Query 1: Opened	Clin: Please confirm that this start date is correct as the participant would have been 28 years old at the time of this diagnosis
Aug-31-2020 17:45:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1983	Initial Entry

***1.d Ongoing:***

Date	Location	User	Value	Reason
Aug-31-2020 17:45:45 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

Time (US & Canada)	(b) (4), (b) (6)
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*l.e*

Date	Location	User	Value	Reason
Feb-26-2021 08:49:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Line/MH Numbe</b> 5 <b>r:</b> <b>Medical History</b> Obesity <b>Term:</b> <b>Start Date:</b> UNK/UNK/ 2010 <b>Ongoing:</b> YES	Transcription Error
Feb-26-2021 08:48:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Numb</b> 5 <b>er:</b> <b>Medical History</b> Obesity <b>Term:</b> <b>Start Date:</b> UNK/UNK/2 010 <b>Ongoing:</b> NO End Date: Dec/1/202 0	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1088

Subject No: 10881126

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1088) PMG Research of Hickory LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

***I.e Line/MH Number:***

Date	Location	User	Value	Reason
Feb-26-2021 08:48:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

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

Date	Location	User	Value	Reason
Feb-26-2021 08:48:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Obesity	Initial Entry

***I.e Start Date:***

Date	Location	User	Value	Reason
Feb-26-2021 08:48:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2010	Initial Entry

***I.e Ongoing:***

Date	Location	User	Value	Reason
Feb-26-2021 08:49:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Transcription Error
Feb-26-2021 08:48:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date: Dec/1/2020	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1088

Subject No: 10881126

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1088) PMG Research of Hickory LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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**1. Date:**

Date	Location	User	Value	Reason
Aug-31-2020 17:46:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/31/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Sep-02-2020 07:28:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed by DM: PM.
Sep-01-2020 18:24:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	Not clinically significant per the PI
Sep-01-2020 04:13:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM1: Please confirm clinical significance. If value is clinically significant, consider reporting medical condition on Medical history page.
Aug-31-2020 18:56:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	Original value is correct
Aug-31-2020 18:55:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Weight 143.6 is outside of Normal Range 25 - 136 for kg or 50 - 300 for lb.
Aug-31-2020 17:46:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> 143.6	Initial Entry

**3. Unit:**

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1088

Subject No: 10881126

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1088) PMG Research of Hickory LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

Date	Location	User	Value	Reason
Aug-31-2020 18:55:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Aug-31-2020 18:55:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> kg	Transcription Error
Aug-31-2020 18:55:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	lb is selected for weight unit, then in is expected to be selected for Height unit. Please check and update data as appropriate.
Aug-31-2020 17:52:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-31-2020 17:46:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	lb is selected for weight unit, then in is expected to be selected for Height unit. Please check and update data as appropriate.
Aug-31-2020 17:46:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Aug-31-2020 18:55:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Aug-31-2020 18:55:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 187.9	New Information
Aug-31-2020 18:55:21 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Height 74 is outside of Normal Range

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Header Text: c4591001

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Form Version: 21-Aug-2020 02:51

Site No: 1088

Subject No: 10881126

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1088) PMG Research of Hickory LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

Time (US & Canada)				140 - 198 for cm or 55 - 80 for in.
Aug-31-2020 17:52:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-31-2020 17:46:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Height 74 is outside of Normal Range 140 - 198 for cm or 55 - 80 for in.
Aug-31-2020 17:46:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 74.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-31-2020 18:55:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cm	New Information
Aug-31-2020 17:52:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> in	updated information
Aug-31-2020 17:46:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-31-2020 18:55:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 40.7	Transcription Error
Aug-31-2020 18:55:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	New Information
Aug-31-2020 18:55:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	New Information

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1088

Subject No: 10881126

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1088) PMG Research of Hickory LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

Aug-31-2020 17:52:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 18.4	updated information
Aug-31-2020 17:46:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-31-2020 18:54:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 97.9 <b>Temperature Unit:</b> F <b>Temperature Locat</b> FOREHE <b>ion::</b> AD	Transcription Error
Aug-31-2020 17:46:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 94.9 <b>Temperature Unit:</b> F <b>Temperature Locat</b> FOREHE <b>ion::</b> AD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-31-2020 17:46:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-31-2020 18:54:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-31-2020 18:54:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 97.9	Transcription Error

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**Header Text:** c4591001

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

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

Aug-31-2020 17:46:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 94.9 F is outside of Normal Range 97 - 99.5 F.
Aug-31-2020 17:46:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 94.9	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Aug-31-2020 17:46:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Aug-31-2020 17:46:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FOREHEAD	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** RANDOMIZATION - eCRF Audit Trail History

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Aug-31-2020 17:48:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/31/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-31-2020 17:48:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 246490	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:** 1088**Site Name:** (1088) PMG Research of Hickory LLC**Subject No:** 10881126**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:22[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-31-2020 17:48:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-31-2020 17:48:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-31-2020 17:49:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-31-2020 17:48:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-31-2020 17:48:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/31/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-31-2020 17:49:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP96ZW	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: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

5.a Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 17:49:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP96ZW	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-31-2020 17:50:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP96ZX	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 17:50:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP96ZX	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-31-2020 17:50:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP96ZY	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 17:50:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP96ZY	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-31-2020 17:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BL9SV8	Initial Entry

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**Header Text:** c4591001

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

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

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

**5.d Sample ID**

Date	Location	User	Value	Reason
Aug-31-2020 17:50:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BL9SV8	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Aug-31-2020 17:51:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BL9SV9	Initial Entry

**5.e Sample ID**

Date	Location	User	Value	Reason
Aug-31-2020 17:51:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BL9SV9	Initial Entry

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**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:** 1088**Site Name:** (1088) PMG Research of Hickory LLC**Subject No:** 10881126**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:22[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-31-2020 17:51:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-31-2020 17:51:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-31-2020 17:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-31-2020 17:51:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-31-2020 17:51:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/31/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-31-2020 17:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP97BN	Initial Entry

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

**5.a Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Aug-31-2020 17:51:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP97BN	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1088

Subject No: 10881126

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1088) PMG Research of Hickory LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Aug-31-2020 17:52:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Aug-31-2020 17:52:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-31-2020 17:52:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Aug-31-2020 17:52:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/31/2020 14:28	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-31-2020 17:52:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Aug-31-2020 17:52:09	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1088

Subject No: 10881126

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1088) PMG Research of Hickory LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

(UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	RIGHT
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7. Route:

Date	Location	User	Value	Reason
Aug-31-2020 17:52:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-31-2020 17:52:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 17:52:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Aug-31-2020 17:52:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

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*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-23-2020 17:30:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Sep/23/2020	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 15-Sep-2020 21:54

Site No: 1088

Subject No: 10881126

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1088) PMG Research of Hickory LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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**1. Date:**

Date	Location	User	Value	Reason
Sep-23-2020 17:30:37 (UTC-05:00) Eastern 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-23-2020 17:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 97.1 <b>Temperature Unit:</b> F <b>Temperature Locat</b> FOREHE <b>ion::</b> AD	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-23-2020 17:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-23-2020 17:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 97.1	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-23-2020 17:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

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090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

Date	Location	User	Value	Reason
Sep-23-2020 17:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<u>Data Entry:</u> FOREHEAD	Initial Entry

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1088**Subject No:** 10881126**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1088) PMG Research of Hickory LLC**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:22[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-23-2020 17:30:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-23-2020 17:30:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-23-2020 17:31:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-23-2020 17:30:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-23-2020 17:30:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/23/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-23-2020 17:31:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP977H	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

**5.a Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-23-2020 17:31:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u><b>Data Entry:</b></u> BP977H	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1088

Subject No: 10881126

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1088) PMG Research of Hickory LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-23-2020 17:32:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-23-2020 17:32:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-23-2020 17:32:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-23-2020 17:32:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/23/2020 08:48	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-23-2020 17:32:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Sep-23-2020 17:32:19	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1088

Subject No: 10881126

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1088) PMG Research of Hickory LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

(UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	RIGHT
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7. Route:

Date	Location	User	Value	Reason
Sep-23-2020 17:32:19 (UTC-05:00) Eastern 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-23-2020 17:32:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSERVATION 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-23-2020 17:32:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-26-2020 14:38:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/26/2020	Initial Entry

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1088**Site Name:** (1088) PMG Research of Hickory LLC**Subject No:** 10881126**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:22[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-26-2020 14:38:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-26-2020 14:38:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-26-2020 14:39:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-26-2020 14:38:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-26-2020 14:38:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/26/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-26-2020 14:39:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BR96X9	Initial Entry

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

5.a Sample ID

Date	Location	User	Value	Reason
Oct-26-2020 14:39:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BR96X9	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-26-2020 14:39:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BR96XB	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-26-2020 14:39:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BR96XB	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-26-2020 14:39:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BR96XC	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-26-2020 14:39:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BR96XC	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-26-2020 14:39:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRZF62	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)



**Header Text:** c4591001

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

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

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

**5.d Sample ID**

Date	Location	User	Value	Reason
Oct-26-2020 14:39:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRZF62	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Oct-26-2020 14:39:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BRZF63	Initial Entry

**5.e Sample ID**

Date	Location	User	Value	Reason
Oct-26-2020 14:39:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRZF63	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Nov/30/2020**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1088**Site Name:** (1088) PMG Research of Hickory LLC**Subject No:** 10881126**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:22[Back to Form](#)**1. Date of Visit**

Date	Location	User	Value	Reason
Dec-01-2020 12:51:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-01-2020 12:47:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Dec-01-2020 12:46:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Dec-01-2020 12:46:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Dec-01-2020 12:46:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/30/2020	Initial Entry

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

Date	Location	User	Value	Reason
Dec-01-2020 12:46:54 (UTC-05:00) Eastern 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 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF on Nov/30/2020 Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Dec-01-2020 12:47:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/30/2020	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Dec-01-2020 12:47:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/29/2020	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Feb-19-2021 13:45:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-19-2021 09:47:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Feb-19-2021 09:47:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Symptom Resolved:  Dec/1/2020	Changed Information
Feb-12-2021 00:39:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	60 days have passed since the Date of First Symptom Started and Ongoing is YES. Please confirm if symptoms are truly

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/30/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

				ongoing. Else, please enter Date of Last Symptom Resolved.
Dec-01-2020 12:47:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Dec-01-2020 12:47:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b> NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Dec-01-2020 12:47:25 (UTC-05:00) Eastern 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
Dec-01-2020 12:47:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Dec-01-2020 12:47:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> NEW OR INCREA : SED COUGH <b>Symptom</b> YES <b>Present:</b>	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF  
on Nov/30/2020 Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

4.b Symptoms:

Date	Location	User	Value	Reason
Dec-01-2020 12:47:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Dec-01-2020 12:47:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Dec-01-2020 12:47:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Dec-01-2020 12:47:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Dec-01-2020 12:47:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.d

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF  
on Nov/30/2020 Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Date	Location	User	Value	Reason
Dec-01-2020 12:47:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS <b>Symptom Present:</b> NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Dec-01-2020 12:47:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Dec-01-2020 12:47:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Dec-01-2020 12:47:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom</b> NEW OR INCREAS <b>s:</b> ED MUSCLE PAIN <b>Symptom</b> NO <b>Present:</b>	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/30/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

4.e Symptoms:

Date	Location	User	Value	Reason
Dec-01-2020 12:47:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Dec-01-2020 12:47:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Dec-01-2020 12:47:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms NEW LOSS OF TASTE OR SMELL Symptom NO Present:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Dec-01-2020 12:47:25 (UTC-05:00) Eastern 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
Dec-01-2020 12:47:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.g

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/30/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

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Generated By: (b) (4)

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Dec-01-2020 12:47:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom</b> NEW OR INCREASED SORE THROAT <b>Symptom</b> NO <b>Present:</b>	Initial Entry
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4.g Symptoms:

Date	Location	User	Value	Reason
Dec-01-2020 12:47:25 (UTC-05:00) Eastern 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
Dec-01-2020 12:47:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Dec-01-2020 12:47:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> DIARRHEA <b>Symptom Present</b> NO <b>:</b>	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/30/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

4.h Symptoms:

Date	Location	User	Value	Reason
Dec-01-2020 12:47:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Dec-01-2020 12:47:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Dec-01-2020 12:47:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms: VOMITIN G Symptom Present NO :	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Dec-01-2020 12:47:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Dec-01-2020 12:47:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail  
on Nov/30/2020

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

**Form Status:**

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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Date	Location	User	Value	Reason
Dec-01-2020 13:22:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	ENTERED IN ERROR

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail  
on Nov/30/2020

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

**Form Status:**

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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Date	Location	User	Value	Reason
Dec-01-2020 13:21:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Nov/30/2020

Form Version: 06-Jul-2020 21:54

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

Site No: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

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**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Dec-01-2020 13:20:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Dec-01-2020 12:47:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Dec-01-2020 13:20:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Dec-01-2020 12:47:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Dec-01-2020 13:20:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Dec-01-2020 12:47:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Dec-01-2020 13:20:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Nov/30/2020

Form Version: 06-Jul-2020 21:54

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

Site No: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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

Dec-01-2020 12:47:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry
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5. Device Type:

Date	Location	User	Value	Reason
Dec-01-2020 13:20:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Dec-01-2020 12:47:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Dec-01-2020 13:20:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Dec-01-2020 12:47:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Dec-01-2020 13:20:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry
Dec-01-2020 12:47:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Dec-01-2020 13:20:43	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 **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Nov/30/2020

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
Dec-01-2020 12:47:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**9. Trade Name Other, Specify:**

Date	Location	User	Value	Reason
Dec-01-2020 13:20:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Dec-01-2020 12:47:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

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**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Dec-01-2020 13:21:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/1/2020	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Dec-01-2020 13:21:33 (UTC-05:00) Eastern 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
Dec-01-2020 13:21:33 (UTC-05:00) Eastern 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
Dec-01-2020 13:21:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RESP SYNDR OME CORONAVIRUS 2	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Dec-01-2020 13:21:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGNOSTIC TE ST	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
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090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

Dec-01-2020 13:21:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> QUIDEL CORPORATION LYR A SARS-COV-2 ASSAY	Initial Entry
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**7. Test Result:**

Date	Location	User	Value	Reason
Dec-01-2020 13:21:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> POSITIVE	Initial Entry



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History  
on Nov/30/2020**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1088**Site Name:** (1088) PMG Research of Hickory LLC**Subject No:** 10881126**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:22[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-01-2020 12:51:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-01-2020 12:51:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-01-2020 12:51:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-01-2020 12:51:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-01-2020 12:51:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/30/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-01-2020 12:51:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: CV22684	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History  
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**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

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**5.a Sample ID**

Date	Location	User	Value	Reason
Dec-01-2020 12:51:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CV22684	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
on Nov/30/2020 Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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**1. Data Origin**

Date	Location	User	Value	Reason
Dec-01-2020 12:52:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-01-2020 12:52:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-01-2020 12:52:07 (UTC-05:00) Eastern 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
Dec-01-2020 12:52:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> self swab collected	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/30/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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*I.a*

Date	Location	User	Value	Reason
Dec-01-2020 12:52:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIA LIST <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

*I.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Dec-01-2020 12:52:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SPECIALIST	Initial Entry

*I.a Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Dec-01-2020 12:52:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*I.b*

Date	Location	User	Value	Reason
Dec-01-2020 12:52:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitio</b> EMERGEN <b>ner:</b> CY ROOM <b>Occurrence of Vi</b> NO <b>sits or Contacts:</b>	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/30/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-01-2020 12:52:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

***1.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-01-2020 12:52:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.c***

Date	Location	User	Value	Reason
Dec-01-2020 12:52:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

***1.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-01-2020 12:52:19 (UTC-05:00) Eastern 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
Dec-01-2020 12:52:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.d***

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/30/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

Date	Location	User	Value	Reason
Dec-01-2020 12:52:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> URGENT CARE <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

*1.d Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Dec-01-2020 12:52:19 (UTC-05:00) Eastern 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
Dec-01-2020 12:52:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*1.e*

Date	Location	User	Value	Reason
Dec-01-2020 12:52:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE CONSULTATION <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/30/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-01-2020 12:52:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> TELEPHONE CONSULTATION	Initial Entry

***1.e Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-01-2020 12:52:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.f***

Date	Location	User	Value	Reason
Dec-01-2020 12:52:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTH ER <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

***1.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-01-2020 12:52:19 (UTC-05:00) Eastern 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
Dec-01-2020 12:52:19 (UTC-05:00) Eastern 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
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090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

Dec-01-2020 12:52:19 (UTC-05:00) Eastern 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: RESPIRATORY TREATMENT - eCRF Audit Trail History on Nov/30/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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**1. What is the treatment Identifier?**

Date	Location	User	Value	Reason
Dec-01-2020 12:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Concomitant Non-drug Treatment Pre-specified:**

Date	Location	User	Value	Reason
Dec-01-2020 12:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Treatment:**

Date	Location	User	Value	Reason
Dec-01-2020 12:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Treatment:**

Date	Location	User	Value	Reason
Dec-01-2020 12:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Dec-01-2020 12:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**6. Ongoing?**

Date	Location	User	Value	Reason
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090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

Dec-01-2020 12:52:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Not Done	Initial Entry
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - eCRF Audit Trail History on Nov/30/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Dec-01-2020 12:52:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID-19 ILLNES S	Initial Entry

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

Date	Location	User	Value	Reason
Dec-11-2020 16:49:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-11-2020 16:41:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Dec-11-2020 16:41:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnosis:</i>  COVID-19  Date of Diagnosis:  Dec/1/2020	Changed Information
Dec-11-2020 14:32:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLIQUEY: Please remove POSITIVE and enter COVID-19 for diagnosis.
Dec-11-2020 14:11:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Dec-11-2020 14:11:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnosis:</i>	New Information

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - eCRF Audit Trail History on Nov/30/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

			POSITIVE FOR COVID-19 Date of Diagnosis: Dec/1/2020	
Dec-11-2020 14:10:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Yes is selected, however, either the diagnosis details or date of diagnosis is missing. Please correct.
Dec-11-2020 14:10:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-11-2020 14:10:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Diagnosis: Dec/1/2020	Transcription Error
Dec-08-2020 10:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLIQUEY: Subject has confirmed COVID-19 (symptoms and positive test), please update diagnosis to COVID-19.
Dec-01-2020 12:52:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-19-2021 16:51:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 5	New Information
Dec-01-2020 12:52:45 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History  
on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

Time (US & Canada)

(b) (4), (b) (6)

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Nov/30/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Dec-01-2020 12:52:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Subcategory of Clinical Event:**

Date	Location	User	Value	Reason
Dec-01-2020 12:52:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Was a diagnosis obtained?**

Date	Location	User	Value	Reason
Dec-01-2020 12:52:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Toxicity Grade:**

Date	Location	User	Value	Reason
Dec-01-2020 12:52:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/30/2020

**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:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Dec-01-2020 12:53:08 (UTC-05:00) Eastern 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
Dec-01-2020 12:53:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Dec-01-2020 12:53:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Dec-01-2020 12:53:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-01-2020 12:53:08 (UTC-05:00) Eastern 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

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/30/2020

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: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

			Not Done::	Not Done
			Lab Normal Range:	Not Done

5.a Sponsor ID:

Date	Location	User	Value	Reason
Dec-01-2020 12:53:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Dec-01-2020 12:53:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Dec-01-2020 12:53:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Dec-01-2020 12:53:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Dec-01-2020 12:53:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

5.b

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

Date	Location	User	Value	Reason
Dec-01-2020 12:53:08 (UTC-05:00) Eastern 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

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit 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: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

5.b Sponsor ID:

Date	Location	User	Value	Reason
Dec-01-2020 12:53:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Dec-01-2020 12:53:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Dec-01-2020 12:53:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Dec-01-2020 12:53:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Dec-01-2020 12:53:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-01-2020 12:53:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/30/2020

**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:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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Header Text: c4591001

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5.c Sponsor ID:

Date	Location	User	Value	Reason
Dec-01-2020 12:53:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Dec-01-2020 12:53:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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5.d

Date	Location	User	Value	Reason
Dec-01-2020 12:53:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Done	Initial Entry

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Date	Location	User	Value	Reason
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5.e

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 10:22

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Date	Location	User	Value	Reason
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5.g

Date	Location	User	Value	Reason
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**Subject No:** 10881126

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**Generated Time (GMT):** 29-Mar-2021 10:22

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**Header Text:** c4591001

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**5.g Sponsor ID:**

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**5.g Test:**

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**5.g Result:**

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**5.g LNMT**

Date	Location	User	Value	Reason
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Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Nov/30/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern 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
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
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**5.a**

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern 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

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

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			Not Done::	Not Done
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5.a Sponsor ID:

Date	Location	User	Value	Reason
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5.a Not Done:

Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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5.b

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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.e

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology -  
on Nov/30/2020 eCRF Audit Trail History

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

			<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 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Nov/30/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

5.e Sponsor ID:

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

			<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 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

5.f Sponsor ID:

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

			<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 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Nov/30/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

5.g Sponsor ID:

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.h

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

			<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 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Nov/30/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

5.h Sponsor ID:

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.h Not Done:

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

5.i

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sponsor-Defined Identifier: Not Done	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

			<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 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Nov/30/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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**5.i Sponsor ID:**

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.i Test:**

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.i Result:**

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.i Not Done:**

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.i LNMT**

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5.j**

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

(UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	<b>Sponsor-Defined Identifier:</b> Not Done
		<b>Test:</b> Not Done
		<b>Result:</b> Not Done
		<b>Not Done:</b> Not Done
		<b>Lab Normal Range:</b> Not Done

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Nov/30/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

**5.j Sponsor ID:**

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

**5.j Test:**

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

**5.j Result:**

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern 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
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

**5.j LNMT**

Date	Location	User	Value	Reason
Dec-01-2020 12:53:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Done	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Nov/30/2020

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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**1. Date:**

Date	Location	User	Value	Reason
Dec-01-2020 12:53:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Dec-01-2020 12:53:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> Not D one <b>Systolic::</b> Not D one <b>Diastolic::</b> Not D one <b>Respiratory Rate in res</b> Not D <b>pitations/minute:</b> one <b>Heart Rate in beats/min</b> Not D <b>ute:</b> one	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Dec-01-2020 12:53:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a Systolic:**

Date	Location	User	Value	Reason
Dec-01-2020 12:53:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a Diastolic:**

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

Date	Location	User	Value	Reason
Dec-01-2020 12:53:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a Respiratory Rate in respirations/minute:**

Date	Location	User	Value	Reason
Dec-01-2020 12:53:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Dec-01-2020 12:53:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail on Nov/30/2020 History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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**I. Date:**

Date	Location	User	Value	Reason
Dec-01-2020 12:53:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Dec-01-2020 12:53:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> Not Done <b>Oxygen Saturation:</b> Not Done	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Dec-01-2020 12:53:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2.a SPO2 Pulse Oximetry %**

Date	Location	User	Value	Reason
Dec-01-2020 12:53:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History on Nov/30/2020

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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**1. Date Time of Assessment:**

Date	Location	User	Value	Reason
Dec-01-2020 12:54:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Arterial Blood Gases PaO2 (mmHg):**

Date	Location	User	Value	Reason
Dec-01-2020 12:54:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. FiO2 (Fraction of Inhaled Oxygen):**

Date	Location	User	Value	Reason
Dec-01-2020 12:54:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/30/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Dec-01-2020 12:54:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Dec-01-2020 12:54:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Dec-01-2020 12:54:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Medication:**

*Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).*

Date	Location	User	Value	Reason
Dec-01-2020 12:54:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Dec-01-2020 12:54:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF  
on Nov/30/2020 Audit Trail History

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

**6. Ongoing?**

Date	Location	User	Value	Reason
Dec-01-2020 12:54:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: IMAGING - eCRF Audit Trail History on Nov/30/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Dec-01-2020 12:54:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Location of Assessment:**

Date	Location	User	Value	Reason
Dec-01-2020 12:54:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**3. Type of Imaging Exam:**

Date	Location	User	Value	Reason
Dec-01-2020 12:54:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

**4. Assessment:**

Date	Location	User	Value	Reason
Dec-01-2020 12:54:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (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:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Oct-26-2020 14:39:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/26/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-26-2020 14:39:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-26-2020 14:39:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)



**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Feb-21-2021 08:02:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-19-2021 09:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Feb-19-2021 09:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/1/2020	Initial Entry
Feb-15-2021 03:12:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2021117426, the date of death was reported as 01Dec2020 in Safety database but missing in CRF. Please confirm correct date of death. If safety update is required, please submit a follow-up form.

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Feb-19-2021 09:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Feb-19-2021 09:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DEATH	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

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Date	Location	User	Value	Reason
Feb-11-2021 09:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1088) PMG Research of Hickory LLC

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**Generated Time (GMT):** 29-Mar-2021 10:22

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Date	Location	User	Value	Reason
Feb-24-2021 19:07:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

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Date	Location	User	Value	Reason
Mar-02-2021 12:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1088

Subject No: 10881126

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1088) PMG Research of Hickory LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

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**1. Category:**

Date	Location	User	Value	Reason
Feb-11-2021 09:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-11-2021 09:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-05-2021 11:17:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 10: Cl osed	Response satisfies query
Mar-02-2021 15:54:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 11: Cl osed	Discrepancy has been closed.
Mar-02-2021 12:50:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 11: A nswer ed	Changed Information
Mar-02-2021 12:50:36 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	auto query (autoquery)	Query 10: A nswer ed	Changed Information

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

(US & Canada)				
Mar-02-2021 12:50:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry</b> : cardiac arrest	Changed Information
Mar-02-2021 10:13:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 10: Re issued :Opened	CLINICAL SAE report states the Death certificate included Hypertension as a cause of death; however, no event is recorded and SAE report states HTN was stable. Please review for any additional adverse event reporting, and if required, update the SAE
Mar-02-2021 10:11:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 9: Closed	Response satisfies query
Mar-02-2021 04:03:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 11: Opened	Multiple concepts in the term CARDIAC ARREST DUE TO CORONARY ARTERY DISEASE. Please split the term into CARDIAC ARREST and CORONARY ARTERY DISEASE and

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

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				submit separately. Thank you.
Mar-01-2021 17:28:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 10: A nsw er ed	New Information
Mar-01-2021 17:28:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 9: Ans wered	New Information
Mar-01-2021 17:28:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry</b> : cardia c arres t due t o coro nary a rtery d isease	New Information
Mar-01-2021 08:18:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 10: O pened	CLINICAL SAE report states the Death certificate included Hypertension as a cause of death; however, no event is recorded and SAE report states HTN was stable. Please review for any additional adverse event reporting, and if required, update the SAE
Mar-01-2021 08:11:47	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 9: Op	Clinical - Event term in Death

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**Header Text:** c4591001

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

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(UTC-05:00) Eastern Time (US & Canada)			ened	Certificate and SAE report is "Cardiac arrest due to Coronary artery disease"; however, event term here is 'Cardiac arrest'. Please review, harmonize reporting, and update where applicable
Feb-25-2021 08:46:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 7: Clo sed	moving query to newly split SAE - COVID half
Feb-25-2021 08:44:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 7: Rei ssued: Opene d	Clinical - please submit a SAE safety update for clinical course of COVID (presenting Sx from COVID illness visit, treatment, XRAY, O2 need, other)
Feb-25-2021 08:26:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 6: Clo sed	Response satisfies query
Feb-24-2021 23:33:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 8: Clo sed	Discrepancy has been closed.
Feb-24-2021 19:04:24 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 8: Ans wered	Changed Information

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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**Site No:** 1088

**Subject No:** 10881126

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Site Name:** (1088) PMG Research of Hickory LLC

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Eastern Time (US & Canada)				
Feb-24-2021 19:04:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 7: Ans wered	Changed Information
Feb-24-2021 19:04:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Ans wered	Changed Information
Feb-24-2021 19:04:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry</b>  i cardia c arres t	Changed Information
Feb-23-2021 11:41:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 8: Op ened	Multiple concepts in the term CARDIAC ARREST AND COVID-19. Split the term into CARDIAC ARREST and COVID-19 and report as separate entries. Thank you.
Feb-23-2021 11:04:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 7: Op ened	Clinical - please submit a SAE safety update for clinical course of COVID (presenting Sx from COVID illness visit, treatment, XRAY, O2 need, other)

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**Header Text:** c4591001

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**Site No:** 1088

**Subject No:** 10881126

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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**Site Name:** (1088) PMG Research of Hickory LLC

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Feb-23-2021 11:00:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 2: Clo sed	Response satisfies query
Feb-23-2021 10:55:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 6: Op ened	Clinical - please separate the 2 fatal SAEs on 2 separate AE lines (they may have different information); both remain on the same SAE report
Feb-23-2021 10:55:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 6: Can didate	Clinical - please separate the 2 fatal SAEs on 2 separate AE lines (they may have different information); both remain on the same SAE report
Feb-23-2021 10:53:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Clo sed	cause of death / fatal event entered
Feb-23-2021 09:03:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 5: Clo sed	Discrepancy has been closed.
Feb-23-2021 07:36:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Ans wered	Changed Information
Feb-23-2021	ACV0PFEINFP6000	auto query	Query	Changed

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**Header Text:** c4591001  
**Visit:** Logs - Unscheduled  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1088  
**Subject No:** 10881126  
**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History  
**Form Status:** Data Complete, Frozen, Verified  
**Site Name:** (1088) PMG Research of Hickory LLC  
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07:36:06 (UTC-05:00) Eastern Time (US & Canada)		(autoquery)	2: Answered	Information
Feb-23-2021 07:36:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Feb-23-2021 07:36:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry</b> : cardiac arrest and COVID-19	Changed Information
Feb-22-2021 13:14:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 2: Reissued: Opened	Clinical Thank you for the SAE term update; please submit this updated event term to the SAE (#2021117426)
Feb-21-2021 09:51:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 5: Opened	Multiple concepts in the term DEATH DUE TO CARDIAC ARREST AND COVID-19. Split the term into DEATH DUE TO CARDIAC ARREST and DEATH DUE TO COVID-19 or split the term into DEATH DUE TO CARDIAC ARREST and COVID-19, as

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**Visit:** Logs - Unscheduled

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**Subject No:** 10881126

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

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				appropriate, and report as two separate entries. Thank you.
Feb-21-2021 09:44:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 4: Closed	Discrepancy has been closed.
Feb-21-2021 05:50:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 4: Opened	Multiple concepts in the term DEATH DUE TO CARDIAC ARREST AND COVID-19. Split the term into DEATH DUE TO CARDIAC ARREST and DEATH DUE TO COVID-19 and report as separate entries. Thank you.
Feb-21-2021 04:00:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 3: Closed	Discrepancy has been closed.
Feb-20-2021 20:36:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Reissued: Opened	Reopen: This 'Adverse Event' contains the term DEATH. If known, please provide the cause of death as the AE term with an outcome of FATAL or clarify.
Feb-19-2021 18:13:08 (UTC-05:00)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 3: Opened	Multiple concepts in the term DEATH DUE TO

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

Eastern Time (US & Canada)				CARDIAC ARREST AND COVID-19. Split the term into DEATH DUE TO CARDIAC ARREST and DEATH DUE TO COVID-19 and report as separate entries. Thank you.
Feb-19-2021 15:00:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Feb-19-2021 15:00:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-19-2021 15:00:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry</b> : Death due to cardiac arrest and COVID-19	New Information
Feb-18-2021 09:11:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 2: Opened	Clinical Please confirm if the site has further information on cause of death from death certificate [confirm if ordered] or if PCP was contacted?

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**Subject No:** 10881126

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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Feb-11-2021 16:19:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW7235687;This 'Adverse Event' contains the term DEATH. If known, please provide the cause of death as the AE term with an outcome of FATAL or clarify.
Feb-11-2021 09:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry</b> : Death	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Mar-10-2021 05:10:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Mar-09-2021 12:35:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	submitting sae safety fup with corrected information
Mar-09-2021 05:14:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON: AER#2021117426,onset date was updated to 29Nov2020 in Safety database however, recorded as 01Dec2020 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.

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4. Start Date Time:

Date	Location	User	Value	Reason
Feb-25-2021 08:45:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	01Dec20 correct for cardiac arrest start date
Feb-24-2021 19:05:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Dec/1/2020 UNK:UNK	Changed Information
Feb-24-2021 07:39:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 2: Answered	Changed data per query
Feb-23-2021 11:00:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical Please submit this updated Start date of 30Nov20 in a SAE Safety update, at START in the event section
Feb-23-2021 10:54:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-23-2021 07:34:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-23-2021 07:34:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Nov/30/2020 UNK:UNK	New Information
Feb-22-2021 13:34:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Start date is 01Dec; however Covid Illness symptoms began 30Nov. In Vaccine study, SAE start date is day event starts; not day it meets serious criteria (item 11 in

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				vaccine SAE instruct). Please review start date & update as appropriate
Feb-11-2021 09:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Dec/1/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-11-2021 09:56:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Dec/1/2020 UNK:UNK	Changed Information
Feb-11-2021 09:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-11-2021 09:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Mar-01-2021 08:12:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	death certificate received & reported

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Mar-01-2021 08:10:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Query closed; will follow for requested obesity information.
Feb-26-2021 08:49:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 4: Answered	Changed data per query
Feb-25-2021 08:50:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	Clinical Please submit the currently available information from COVID illness pages. Subsequent update based on Med Records can be added later
Feb-25-2021 08:49:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	SAE report states NO autopsy performed
Feb-24-2021 07:31:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 3: Answered	still awaiting medical records/death certificate
Feb-24-2021 07:31:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 2: Answered	still awaiting medical records/death certificate
Feb-23-2021 11:05:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	Clinical - subject had a BMI of 40.7 at study entry; considering clinical relevance to both COVID and cardiac disease, review for relevance as a prior Med history condition, and submit to SAE Med Hx if appropriate

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Feb-22-2021 16:52:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Clinical - please confirm if there was an autopsy performed for this death, and report the autopsy status (yes/no) in a SAE safety followup
Feb-22-2021 13:31:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical Please report all COVID tests (date, results, Pfizer central swab or local inpt/outpt test, with kit name if available) to SAE
Feb-15-2021 03:03:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-11-2021 09:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Death: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-11-2021 09:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associate d with congenital anomaly or birth defect?  NO  Did this serious event result i n death?  YES  Did this serious event require or prolong hospitalization?  NO	Initial Entry

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			<p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>YES</p> <p>Other medically important serious event</p> <p>NO</p>
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**8. Is this adverse event the result of a study Medication Error?**

*If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Feb-11-2021 09:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Feb-11-2021 09:57:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  unknown	Changed Information
Feb-11-2021 09:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:	Initial Entry

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			CONCOMITANT NON-DRUG TREATMENT	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-11-2021 09:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-11-2021 09:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-11-2021 09:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Feb-19-2021 13:39:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-19-2021 09:50:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 3: Answered	Changed data per query
Feb-11-2021 23:15:18	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Op	DMW7235616;The outcome of this AE

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(UTC-05:00) Eastern Time (US & Canada)			ened	is selected as FATAL, but there are no Disposition eCRFs with a 'Status' of DEATH. Please review and update as appropriate.
Feb-11-2021 10:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Clo sed	Close Auto Query
Feb-11-2021 09:56:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Clo sed	Close Auto Query
Feb-11-2021 09:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Op ened	Response to "What was the outcome of this adverse event?" is 'Fatal' but Date of Collection / Notification of Death on the Death Details form is not completed. Please review and update as appropriate.
Feb-11-2021 09:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Op ened	For AE Death: Response to "What was the outcome of this adverse event?" is 'Fatal' but "Is the adverse event still ongoing?" is marked 'Yes'.

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Feb-11-2021 09:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry</b> : FATA L	Initial Entry
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**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Feb-11-2021 09:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Feb-15-2021 03:03:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021117426	Initial Entry

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**1. Category:**

Date	Location	User	Value	Reason
Feb-24-2021 19:07:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-24-2021 19:07:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-05-2021 11:19:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-01-2021 17:28:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-25-2021 08:46:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical - please submit a SAE safety update for clinical course of COVID (presenting Sx from COVID illness visit, treatment, XRAY, O2 need, other)
Feb-24-2021 19:07:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> COVID-19	Initial Entry

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Date	Location	User	Value	Reason
Mar-10-2021 09:47:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-09-2021 12:17:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	Site submitted 3 separate SAE follow up reports for each event and each event is separated in Inform. Kindly confirm what is pending as it is unclear.
Mar-09-2021 05:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Mar-09-2021 05:08:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	SAE RECON: AER#2021117426 , per latest SAE listing onset date for COVID 19 is still recorded as 01Dec2020. Please confirm if a follow up SAE form was submitted indicating the correct onset date of 29Nov2020 per previous response.
Mar-05-2021 09:09:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-05-2021 09:08:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Clinical - in order to report separate start dates to SAE, please split up the composite term into 2 Events with separate event tabs (Cardiac arrest; COVID)

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Mar-04-2021 13:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 2: Answered	this has already been submitted as of this morning
Mar-04-2021 13:18:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	SAE RECON1: Thanks for confirming. Please submit an SAE follow up with the updated start date since onset date reported in safety database is 01DEC2020 or else clarify.
Mar-04-2021 07:37:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 2: Answered	Original value is correct
Mar-03-2021 06:00:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON: AER#2021117426 ,onset date was recorded as 01Dec2020 in Safety database however, recorded as 29Nov2020 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Mar-01-2021 17:29:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-25-2021 08:47:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical - Thank you; please enter the updated COVID SAE start date in the SAE report Event section under 'START'

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Feb-24-2021 19:07:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Nov/29/2020 UNK:UNK	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-24-2021 19:07:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Dec/1/2020 04:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-24-2021 19:07:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-26-2021 05:02:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-24-2021 19:07:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE COVID-19: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-24-2021 19:07:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associated	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1088

Subject No: 10881126

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1088) PMG Research of Hickory LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

			with congenital anomaly or birth defect?	
			NO	
			Did this serious event result in death?	
			YES	
			Did this serious event require or prolong hospitalization?	
			NO	
			Did this serious event result in persistent or significant disability/incapacity?	
			NO	
			Is this serious event life threatening?	
			YES	
			Other medically important serious event	
			NO	

**8. Is this adverse event the result of a study Medication Error?**

*If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Feb-24-2021 19:07:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Feb-24-2021 19:07:00 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1088

Subject No: 10881126

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1088) PMG Research of Hickory LLC

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Time (US & Canada)		(b) (4), (b) (6)	If Not Related to study treatment(s), this event is due to:  OTHER  If Other, specify:  COVID-19
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-24-2021 19:07:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-24-2021 19:07:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-24-2021 19:07:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Feb-24-2021 19:07:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FATAL	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Feb-24-2021 19:07:38 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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**Site No:** 1088

**Subject No:** 10881126

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Site Name:** (1088) PMG Research of Hickory LLC

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Time (US & Canada)				
Feb-24-2021 19:07:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Changed Information
Feb-24-2021 19:07:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	More than 1 AE for this patient has "Did the adverse event cause the subject to be discontinued from the study?" marked as 'Yes'.
Feb-24-2021 19:07:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Feb-26-2021 05:02:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021117426	Initial Entry

090177e196ae3f99\Final\Final On: 01-Apr-2021 05:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1088

Subject No: 10881126

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Queries, Verified

Site Name: (1088) PMG Research of Hickory LLC

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**1. Category:**

Date	Location	User	Value	Reason
Mar-02-2021 12:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Mar-02-2021 12:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-10-2021 05:11:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-09-2021 15:10:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SAE form has been resubmitted with revisions
Mar-08-2021 03:51:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2021117426 Coronary Artery Disease is not recorded in Safety database but recorded as separate event in inform. Please confirm and submit a follow up SAE form to report event in Safety database.
Mar-02-2021 12:54:55 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Coronary Artery Disease	Initial Entry

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Header Text: c4591001

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Subject No: 10881126

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Queries, Verified

Site Name: (1088) PMG Research of Hickory LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:22

Time (US & Canada)	(b) (4), (b) (6)
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4. Start Date Time:

Date	Location	User	Value	Reason
Mar-10-2021 09:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Start for event CAD is 01Dec20; however Med Hx gives start in 1983 (which applies as no Worsening occurred). In Vaccine study, SAE start date is day event starts; not day it meets serious criteria (item 11 in vaccine SAE instructs); please update
Mar-02-2021 12:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	<b>Data Entry:</b> Dec/1/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-02-2021 12:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Dec/1/2020 16:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-02-2021 12:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4	Initial Entry

7. Is the adverse event serious?

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Site No: 1088

Subject No: 10881126

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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*If Yes, NOTIFY PFIZER IMMEDIATELY.*

*Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).*

Date	Location	User	Value	Reason
Mar-03-2021 05:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-02-2021 12:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Coronary Artery Disease: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Mar-02-2021 12:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birth defect?  NO  Did this serious event result in death?  YES  Did this serious event require or prolong hospitalization?  NO  Did this serious event result in persistent or significant disability/ incapacity?  NO  Is this serious event life threatening?	Initial Entry

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Site No: 1088

Subject No: 10881126

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Queries, Verified

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			YES	
			Other medically important serious event	
			NO	

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Mar-02-2021 12:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-05-2021 16:29:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	clinical: requested assistance from ICON to resolve
Mar-05-2021 15:27:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	There is no mention of worsening of underlying CAD in the subject's medical records.
Mar-04-2021 10:48:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	clinical: subject has a past history of CAD noted on MedHx CRF. Is this AE due to 'worsening' of underlying cardiac disease? If so, pls update AE term to indicate this and consider updating causality other=underlying CAD. Thanks
Mar-04-2021 10:35:11	ACV0PFEINFP6000	auto query	Query 1: Answered	New Information

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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1088**Subject No:** 10881126**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Queries, Verified**Site Name:** (1088) PMG Research of Hickory LLC**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:22

(UTC-05:00) Eastern Time (US & Canada)		(autoquery)		
Mar-04-2021 10:35:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  cardiac arrest	New Information
Mar-04-2021 09:09:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: pls advise what concomitant drug implicated. Thanks
Mar-02-2021 12:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  CONCOMITANT DRUG TREATMENT	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Mar-02-2021 12:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Mar-02-2021 12:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

Mar-02-2021 12:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Mar-02-2021 12:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FATAL	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Mar-02-2021 13:47:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-02-2021 13:47:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Changed Information
Mar-02-2021 12:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	More than 1 AE for this patient has "Did the adverse event cause the subject to be discontinued from the study?" marked as 'Yes'.
Mar-02-2021 12:54:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Mar-03-2021 05:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021117426	Initial Entry

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**Header Text:** c4591001**Visit:** Disposition - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1088**Subject No:** 10881126**Generated By:** (b) (4)**Form:** DEATH DETAILS CODED - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1088) PMG Research of Hickory LLC**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:22[Back to Form](#)***1. Date of Collection / Notification of Death:***

Date	Location	User	Value	Reason
Feb-19-2021 18:04:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-19-2021 17:59:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-19-2021 16:55:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-19-2021 16:54:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Feb-12-2021 17:21:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY: Death form is entered but disposition follow-up (FUP) is not complete. Please verify and update the FUP form, else clarify.
Feb-12-2021 17:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Please report cause of death.
Feb-11-2021 10:00:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/1/2020	Initial Entry

***2.a***

Date	Location	User	Value	Reason
Feb-19-2021 16:55:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Cause of De</b> PRIMARY CAU <b>ath Status:</b> SE OF DEATH	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1088

Site Name: (1088) PMG Research of Hickory LLC

Subject No: 10881126

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:22

			<b>Cause of Death:</b> Cardiac arrest	
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**2.a Cause of Death Status:**

Date	Location	User	Value	Reason
Feb-19-2021 16:55:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CAUSE OF DEATH	Initial Entry

**2.a Cause of Death:**

Date	Location	User	Value	Reason
Feb-19-2021 16:55:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Cardiac arrest	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Feb-19-2021 16:55:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Cause of Death Status: SECONDARY CAUSE OF DEATH Cause of Death: COVID-19	Initial Entry

**2.b Cause of Death Status:**

Date	Location	User	Value	Reason
Feb-19-2021 16:55:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SECONDARY CAUSE OF DEATH	Initial Entry

**2.b Cause of Death:**

Date	Location	User	Value	Reason
Feb-19-2021 16:55:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COVID-19	Initial Entry

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Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1088

Subject No: 10881126

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1088) PMG Research of Hickory LLC

Subject Initials: ---

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**1. Subject Status**

Date	Location	User	Value	Reason
Feb-19-2021 09:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Initial Entry
Oct-26-2020 14:39:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-31-2020 17:48:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-31-2020 17:42:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Feb-19-2021 09:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Dec/1/2020	Initial Entry
Feb-11-2021 19:05:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-11-2021 09:45:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-08-2021 12:32:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL - Subject has a SAE report (#2021117426) for an event of Death Cause Unknown. Please record the adverse event on the AE CRF.

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**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1088

**Subject No:** 10881126

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

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:22

Oct-26-2020 14:39:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/26/2020	Initial Entry
Aug-31-2020 17:48:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/31/2020	Initial Entry
Aug-31-2020 17:42:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/31/2020	Initial Entry

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**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

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

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

**Site No:** 1088

**Site Name:** (1088) PMG Research of Hickory LLC

**Subject No:** 10881126

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:22

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*I. Casebook Signature*

Date	Location	User	Value	Reason
Nov-02-2020 11:27:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry