

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** COHORT\_SELECTION

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Cohort Selection**

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

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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** MAIN INFORMED CONSENT

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/17/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** DEMOGRAPHY

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[12521010]
2.	Birth Date:	(b) (6)/1939
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:	

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**Header Text:** c4591001

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

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** DATE OF VISIT

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

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

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject Initials:** ---

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

[Form Comments](#)

**Inclusion Criteria Not Met**

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

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

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

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation /Death	Aug/17/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1252

Subject No: 12521010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject Initials: ---

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

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Seasonal Allergies]
	Start Date:	Apr/18/2018
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Vertigo]
	Start Date:	Oct/2/2019
	Ongoing:	YES

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**Header Text:** c4591001

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

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Aug/17/2020
2.	Weight:	[165.0]
3.	Unit:	LB
4.	Height:	[63.0]
5.	Unit:	in
6.	Body Mass Index:	[29.2]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[98.6]
	Unit:	F
	Temperature Location:	ORAL CAVITY

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**Header Text:** c4591001

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

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** RANDOMIZATION

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Aug/17/2020
2.	Randomization Number:	[230749]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BNWG1K]
5.b	Sample ID	[BNWG1L]
5.c	Sample ID	[BPYXM0]
5.d	Sample ID	[BPYXM1]
5.e	Sample ID	[BPYXM2]

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**Header Text:** c4591001

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

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

**Site No:** 1252

**Subject No:** 12521010

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

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

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPYXLZ]
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090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** VACCINATION

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/17/2020 15:44
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** DATE OF VISIT

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/8/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 21-Aug-2020 02:52

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

2.h	Symptom:	NEW OR WORSENERD JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/8/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[98.3]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1252

**Subject No:** 12521010

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

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

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/8/2020
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	[BPYXZK]
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090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** VACCINATION

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

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

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** DATE OF VISIT

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Oct/5/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

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

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 21-Aug-2020 02:52

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

2.h	Symptom:	NEW OR WORSENERD JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/5/2020
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	[BPYY1Y]
5.b	Sample ID	[BPYY1Z]
5.c	Sample ID	[BPYY20]
5.d	Sample ID	[BNWG3X]
5.e	Sample ID	[BNWG3Y]

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject Initials:** ---

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

**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:** 1252

**Subject No:** 12521010

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject Initials:** ---

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

**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:** 1252

**Subject No:** 12521010

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject Initials:** ---

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

**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:** 1252

**Subject No:** 12521010

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET  
Dec/25/2020

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

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Dec/25/2020
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	COVID_A

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19  
Dec/25/2020

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Signs and Symptoms**

1.	Date of Assessment:	Dec/25/2020
2.	Date of First Symptom Started:	Dec/25/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Dec/26/2020

**Symptoms**

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

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19  
Dec/25/2020

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

**Symptoms - Other**

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

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

**Form:** MICROBIOLOGY SPECIMEN

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Dec/25/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN  
Dec/25/2020

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

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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**Microbiology Specimen**

1.	Actual Date of Collection:	Dec/25/2020
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	ABBOTT DIAGNOSTICS ID NOW COVID-19
7.	Test Result:	POSITIVE
8.	Comments/Findings/Details:	[Hospital reported that the nasal swab came back positive.]
9.	Trade Name Other, Specify:	[ ]

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF  
Dec/25/2020

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

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Subject went to hospital emergency and never was able to do a SELF SWAB HOME KIT. The subject passed!]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
Dec/25/2020

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

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Hospital did a Nasal Swab when subject was admitted. The kit used was ABBOTT ID NOW SARS-COV-2 POINT OF CARE according to medical records. The site never collected a Nasal Swab or a Self Nasal swab.]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION  
Dec/25/2020**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete**Site No:** 1252**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine**Subject No:** 12521010**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[eCRF Audit Trail History](#)**Health Care Utilization**

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

**Health Care Utilization Other**

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

**Health Care Utilization**

3.	Has the subject been hospitalized due to potential COVID-19 illness?	YES Has the subject been in intensive care due to potential COVID-19 illness? NO
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**Header Text:** c4591001

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

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** HOSPITALIZATION DETAILS

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject Initials:** ---

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

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1.	HOSPITALIZATION STATUS	HOSPITAL	Dec/25/2020	NO Discharge Date: Dec/26/2020	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** HOSPITALIZATION DETAILS  
Dec/25/2020

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

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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**Hospitalization Details**

1.	Hospitalization Category:	HOSPITALIZATION STATUS
2.	Hospitalization Term:	HOSPITAL
3.	Admission Date:	Dec/25/2020
4.	Ongoing?	NO Discharge Date: Dec/26/2020

**Header Text:** c4591001

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

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.	1	YES	HIGH FLOW OXYGEN THERAPY	HIGH FLOW OXYGEN THERAPY	Dec/26/2020	<a href="#">Repeating Pages</a>



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT  
Dec/25/2020

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

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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**Respiratory Treatment**

1.	What is the treatment Identifier?	[1]
2.	Concomitant Non-drug Treatment Pre-specified:	YES
3.	Treatment:	HIGH FLOW OXYGEN THERAPY
4.	Treatment:	[HIGH FLOW OXYGEN THERAPY]
5.	Start Date:	Dec/26/2020
6.	Ongoing?	NO End Date: Dec/26/2020

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS  
Dec/25/2020

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

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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**Illness Details**

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [Pneumonia due to Covid 19]  Date of Diagnosis: Dec/25/2020
3.	Toxicity Grade:	5

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	SEVERE COVID-19 ILLNESS	SIGNIFICANT ACUTE RENAL DYSFUNCTION	<p>YES</p> <p><i>Diagnosis:</i></p> <p>Acute kidney disease</p> <p>Start Date:</p> <p>Dec/25/2020</p> <p>Ongoing?:</p> <p>NO</p> <p>End Date:</p> <p>Dec/26/2020</p>	5	<a href="#">Repeating Pages</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE  
Dec/25/2020

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

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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**Illness Details**

1.	Category of Clinical Event:	SEVERE COVID-19 ILLNESS
2.	Subcategory of Clinical Event:	SIGNIFICANT ACUTE RENAL DYSFUNCTION
3.	Was a diagnosis obtained?	YES Diagnosis: [Acute kidney disease]  Start Date: Dec/25/2020  Ongoing?: NO  End Date: Dec/26/2020
4.	Toxicity Grade:	5

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

#	Category for Lab Test	Vendor Name	Collecti on Date :	Specim en Type	Lab Result			Form Instan ce
1.	CLINICAL CHEMISTR Y	McLeod Loris Hospital 3611 Mitchell Street Loris SC 295 69	Dec/25/ 2020	BLOO D	<b>Sponsor-Defi ned Identifie r</b>	<b>Test:</b>	<b>Res ult:</b>	<a href="#">Repeating Pages</a>
					329	C Reactive Prote in_PX329	24.7	
					30	Alanine Aminotr ansferase_PX30	[ ]	
					28	Aspartate Amino transferase_PX2 8	[ ]	
						Alkaline Phosph atase_PX35		
					21	Bilirubin_PX21	1.8	
					47	Blood Urea Nitr ogen_PX47	91	
					48	Creatinine_PX4 8	4.15	

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 10-Dec-2020 02:24

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
2. DELETED					Sponsor-Defined Identifier	Test:	Result:	<a href="#">Repeating Pages</a>
						C Reactive Protein_PX329		
					30	Alanine Aminotransferase_PX30	[ ]	
					28	Aspartate Aminotransferase_PX28	[ ]	
						Alkaline Phosphatase_PX35		
						Bilirubin_PX21		
						Blood Urea Nitrogen_PX47		
						Creatinine_PX48		

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
Dec/25/2020

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

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**Lab Chemistry Details**

1.	Lab Panel:	CLINICAL CHEMISTRY
2.	Laboratory Name and Address	[McLeod Loris Hospital 3611 Mitchell Street Loris SC 29569]
3.	Collection Date:	Dec/25/2020
4.	Specimen Type:	BLOOD

**Lab Result**

5.a	Sponsor ID:	[329]
	Test:	C Reactive Protein_PX329
	Result:	[24.7]
	Not Done:	
	LNMT	Low [0.0] High [1.0] Unit mg/dL
5.b	Sponsor ID:	[30]
	Test:	Alanine Aminotransferase_PX30
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
Dec/25/2020

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

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

5.c	Sponsor ID:	[28]
	Test:	Aspartate Aminotransferase_PX28
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit
5.d	Sponsor ID:	[ ]
	Test:	Alkaline Phosphatase_PX35
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit
5.e	Sponsor ID:	[21]
	Test:	Bilirubin_PX21
	Result:	[1.8]
	Not Done:	
	LNMT	Low [0.1] High [1.2] Unit mg/dL

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
Dec/25/2020

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

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

5 f	Sponsor ID:	[47]
	Test:	Blood Urea Nitrogen_PX47
	Result:	[91]
	Not Done:	
	LNMT	Low [9] High [20] Unit mg/dL
5.g	Sponsor ID:	[48]
	Test:	Creatinine_PX48
	Result:	[4.15]
	Not Done:	
	LNMT	Low [0.66] High [1.25] Unit mg/dL

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
Dec/25/2020

Form Version: 10-Dec-2020 02:24

Form Status: Incomplete, Data Complete, Deleted

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

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

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**Lab Chemistry Details**

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

**Lab Result**

5.a	Sponsor ID:	[ ]
	Test:	<del>C Reactive Protein_PX329</del>
	Result:	[ ]
	Not Done:	
	LNMT	<del>Low</del> [ ] <del>High</del> [ ] <del>Unit</del>
5.b	Sponsor ID:	[30]
	Test:	<del>Alanine Aminotransferase_PX30</del>
	Result:	[ ]
	Not Done:	<del>NOT DONE</del>
	LNMT	<del>Low</del> [ ] <del>High</del> [ ] <del>Unit</del>

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5-e	Sponsor ID:	[28]
	Test:	Aspartate Aminotransferase_PX28
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit
5-d	Sponsor ID:	[ ]
	Test:	Alkaline Phosphatase_PX35
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit
5-e	Sponsor ID:	[ ]
	Test:	Bilirubin_PX21
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit
5-f	Sponsor ID:	[ ]
	Test:	Blood Urea Nitrogen_PX47
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

5.g	Sponsor ID:	[ ]
	Test:	Creatinine_PX48
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form Version: 21-Aug-2020 02:51

Site No: 1252

Subject No: 12521010

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject Initials: ---

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

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.		Not Applicable	Not Applicable		Sponsor-Defined Identifier	Test:	Result:	<a href="#">Repeating Pages</a>
						Hemoglobin_PX1		
						Hematocrit_PX2		
						Erythrocytes_PX3	[ ]	
						Platelets_PX5		
						Leukocytes_PX7	[ ]	
						Neutrophils_PX608		
						Eosinophils_PX609		
						Monocytes_PX612		
						Basophils_PX610		
						Lymphocytes_PX611		

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 10-Dec-2020 02:28

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
2.	HEMATOLOGY	McLeod Loris Hospital 3611 Mitchell Street Loris SC 29569	Dec/25/2020	BLOOD	<b>Sponsor-Defined Identifier</b>	<b>Test:</b>	<b>Result:</b>	<a href="#">Repeating Pages</a>
					1	Hemoglobin_PX1	9.2	
					2	Hematocrit_PX2	27.6	
					3	Erythrocytes_PX3	[ ]	
					5	Platelets_PX5	125	
					7	Leukocytes_PX7	[ ]	
					608	Neutrophils_PX608	5.4	
					609	Eosinophils_PX609	0.3	
					612	Monocytes_PX612	0.5	
					610	Basophils_PX610	0.2	
611	Lymphocytes_PX611	0.6						

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology Dec/25/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

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**Laboratory Data Hematology**

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

**Lab Result**

5.a	Sponsor ID:	[ ]
	Test:	Hemoglobin_PX1
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit
5.b	Sponsor ID:	[ ]
	Test:	Hematocrit_PX2
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
Dec/25/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

5.c	Sponsor ID:	[ ]
	Test:	Erythrocytes_PX3
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit
5.d	Sponsor ID:	[ ]
	Test:	Platelets_PX5
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit
5.e	Sponsor ID:	[ ]
	Test:	Leukocytes_PX7
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
Dec/25/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

5.f	Sponsor ID:	[ ]
	Test:	Neutrophils_PX608
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit
5.g	Sponsor ID:	[ ]
	Test:	Eosinophils_PX609
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit
5.h	Sponsor ID:	[ ]
	Test:	Monocytes_PX612
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
Dec/25/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

5.i	Sponsor ID:	[ ]
	Test:	Basophils_PX610
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit
5.j	Sponsor ID:	[ ]
	Test:	Lymphocytes_PX611
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
Dec/25/2020

**Form Version:** 10-Dec-2020 02:28

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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**Laboratory Data Hematology**

1.	Lab Panel:	HEMATOLOGY
2.	Laboratory Name and Address	[McLeod Loris Hospital 3611 Mitchell Street Loris SC 29569]
3.	Collection Date:	Dec/25/2020
4.	Specimen Type:	BLOOD

**Lab Result**

5.a	Sponsor ID:	[1]	<a href="#">Comments</a>
	Test:	Hemoglobin_PX1	
	Result:	[9.2]	<a href="#">Comments</a>
	Not Done:		<a href="#">Comments</a>
	LNMT	Low [14.0] High [18.0] Unit g/dL	<a href="#">Comments</a>
5.b	Sponsor ID:	[2]	<a href="#">Comments</a>
	Test:	Hematocrit_PX2	
	Result:	[27.6]	<a href="#">Comments</a>
	Not Done:		<a href="#">Comments</a>
	LNMT	Low [40.0] High [52.0] Unit %	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
Dec/25/2020

**Form Version:** 10-Dec-2020 02:28

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

5.c	Sponsor ID:	[3]
	Test:	Erythrocytes_PX3
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit
5.d	Sponsor ID:	[5]
	Test:	Platelets_PX5
	Result:	[125]
	Not Done:	
	LNMT	Low [150] High [450] Unit /uL
5.e	Sponsor ID:	[7]
	Test:	Leukocytes_PX7
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
Dec/25/2020

**Form Version:** 10-Dec-2020 02:28

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

5 f	Sponsor ID:	[608]
	Test:	Neutrophils_PX608
	Result:	[5.4]
	Not Done:	
	LNMT	Low [1.9] High [7.6] Unit 10^9/L
5.g	Sponsor ID:	[609]
	Test:	Eosinophils_PX609
	Result:	[0.3]
	Not Done:	
	LNMT	Low [0.00] High [0.50] Unit 10^9/L
5.h	Sponsor ID:	[612]
	Test:	Monocytes_PX612
	Result:	[0.5]
	Not Done:	
	LNMT	Low [0.2] High [1.5] Unit 10^9/L

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
Dec/25/2020

**Form Version:** 10-Dec-2020 02:28

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

5.i	Sponsor ID:	[610]
	Test:	Basophils_PX610
	Result:	[0.2]
	Not Done:	
	LNMT	Low [0.0] High [0.2] Unit 10^9/L
5.j	Sponsor ID:	[611]
	Test:	Lymphocytes_PX611
	Result:	[0.6]
	Not Done:	
	LNMT	Low [1.1] High [4.8] Unit 10^9/L

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**Header Text:** c4591001

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

**Form:** VITAL SIGNS - COVID

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

#	Date:	Vital Signs Details			Form Instance
1.	Dec/25/2020	<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>
		1	124	68	

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**Header Text:** c4591001

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

**Form:** VITAL SIGNS - COVID

**Form Version:** 10-Dec-2020 02:25

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID  
Dec/25/2020

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

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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**Vital Signs**

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

**Vital Signs Details**

2.a	Record Identifier:	1
	Systolic:	[124]
	Diastolic:	[68]
	Respiratory Rate in respirations/minute:	[20]
	Heart Rate in beats/minute:	[79]

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID  
Dec/25/2020

**Form Version:** 10-Dec-2020 02:25

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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**Vital Signs**

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

**Vital Signs Details**

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

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**Header Text:** c4591001

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

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

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

#	Date:	Vital Signs Details		Form Instance
1.	Dec/25/2020	<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>
		1	98.0	

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**Header Text:** c4591001

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

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

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

#	Date:	Vital Signs Details		Form Instance
2. DELETED	Dec/25/2020	<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>
		1	98.0	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
Dec/25/2020

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

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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**Vital Signs**

1.	Date:	Dec/25/2020	<a href="#">Comments</a>
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**Vital Signs Details**

2.a	Record Identifier:	1	
	SPO2 Pulse Oximetry %	[98.0]	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
Dec/25/2020

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

**Form Status:** Data Complete, Deleted

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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**Vital Signs**

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

**Vital Signs Details**

2.a	Record Identifier:	±	
	SPO2 Pulse Oximetry %	[98.0]	<a href="#">Comments</a>

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**Header Text:** c4591001

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

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS  
Dec/25/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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**Oxygenation Parameters**

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

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**Header Text:** c4591001

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

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS  
Dec/25/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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**Concomitant Medications**

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

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**Header Text:** c4591001

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

**Form:** IMAGING

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Dec/25/2020	CHEST	X-RAY	ABNORMAL <i>If abnormal, specify findings:</i>  An enlarged heart	<a href="#">Repeating Pages</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** IMAGING  
Dec/25/2020

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

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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**Imaging**

1.	Date of Assessment:	Dec/25/2020	<a href="#">Comments</a>
2.	Location of Assessment:	CHEST	<a href="#">Comments</a>
3.	Type of Imaging Exam:	X-RAY	<a href="#">Comments</a>
4.	Assessment:	ABNORMAL If abnormal, specify findings: [An enlarged heart]	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Dec/26/2020

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

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

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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**Date of Visit**

1.	Date of Visit	Dec/26/2020	<a href="#">Comments</a>
2.	Erroneous Visit	ERRONEOUS VISIT	<a href="#">Comments</a>

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	Not Done	<a href="#">Comments</a>
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**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Dec/26/2020

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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**Electronic Sample Tracking**

1.	Data Origin	Not Done _____	<a href="#">Comments</a>
2.	Sample Type	Not Done _____	<a href="#">Comments</a>
3.	Sample Collected?	Not Done _____	<a href="#">Comments</a>
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	Not Done _____ [ ]	<a href="#">Comments</a>

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	Not Done _____ [ ]
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**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** UNPLANNED VISIT

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

**Form Status:** Not Started

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

**Unplanned Assessments**

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



**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** DISPOSITION - TREATMENT

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Oct/5/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

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**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** DISPOSITION - FOLLOW-UP

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

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**Disposition - Follow-Up**

1.	Date of Completion/Discontinuation /Death :	Dec/26/2020
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:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

3.	COVID-19 Repeat Swab:	
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090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**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:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Scalp Laceration	Dec/8/2020 19:05	NO End Date Time: Dec/8/2020 20:30	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	Pneumonia due to COVID-19	Dec/25/2020 22:03	NO End Date Time: Dec/26/2020 09:55	<a href="#">Repeating Pages</a>
3.	ADVERSE EVENT	3	Acute Renal failure	Dec/25/2020 22:03	NO End Date Time: Dec/26/2020 09:55	<a href="#">Repeating Pages</a>

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Scalp Laceration]
4.	Start Date Time:	Dec/8/2020 19:05
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/8/2020 20:30
6.	Toxicity Grade:	1
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Accident]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

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

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Pneumonia due to COVID-19]
4.	Start Date Time:	Dec/25/2020 22:03
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/26/2020 09:55
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? YES  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? YES  Other medically important serious event NO
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:** 1252

**Subject No:** 12521010

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

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: [Pneumonia]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	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	[2020518879]

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Acute Renal failure]
4.	Start Date Time:	Dec/25/2020 22:03
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/26/2020 09:55
6.	Toxicity Grade:	2
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Kidney damage]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

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

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** MEDICATION ERROR

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

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**Medication Error**

1.	Category:	Not Applicable _____	<a href="#">Comments</a>
2.	Medication Error (Type of Medication Error):	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	Start Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Is the medication error still ongoing?	Not Applicable _____	<a href="#">Comments</a>
5.	Latest Action Taken with Study Treatment:	Not Applicable _____	<a href="#">Comments</a>
6.	Was a Concomitant Medication given?	Not Applicable _____	<a href="#">Comments</a>
7.	Was a Non-Drug Treatment given?	Not Applicable _____	<a href="#">Comments</a>
8.	Did the Medication Error cause the subject to be discontinued from the study?	Not Applicable _____	<a href="#">Comments</a>
9.	Was this medication error associated with any adverse events?	Not Applicable _____	<a href="#">Comments</a>
10.	Serious Adverse Event Number: For Pfizer Use Only	Not Applicable _____ [ ]	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1252

**Subject No:** 12521010

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

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

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject Initials:** ---

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

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**Concomitant Medications**

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

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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**Concomitant Medications**

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

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1252

**Subject No:** 12521010

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

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

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject Initials:** ---

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

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**Concomitant Medications**

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

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1252

Subject No: 12521010

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Data Complete, Frozen, Verified

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject Initials: ---

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

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**Concomitant Medications**

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

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** RADIATION TREATMENT

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

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**Radiation Treatment**

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

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** TRANSFUSIONS

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

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

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**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VITAL SIGNS - TEMP

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

**Form Status:** Not Started

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

**Vaccination**

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

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**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

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

**Form Status:** Not Started

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 6

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

**Form Status:** Not Started

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - Unscheduled **Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - Unscheduled **Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

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

**Form Status:** Not Started

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

**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:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (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:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)



**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:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

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

**Form:** FURTHER VACCINATION CONFIRMATION

**Form Version:** 10-Dec-2020 02:25

**Form Status:** Not Started

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

**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:** 1252

**Subject No:** 12521010

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

**Form:** TREATMENT UNBLINDED

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

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

Treatment Unblinded			
1.	Date Treatment Unblinded :	Not Applicable _____ //	<a href="#">Comments</a>
2.	Primary Reason for Unblinding:	Not Applicable _____	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** WITHDRAWAL OF CONSENT

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Withdrawal Of Consent**

1.	Withdrawal of Consent Date :	Not Applicable	<a href="#">Comments</a>
		//	

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** DEATH DETAILS CODED

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Death Details**

1.	Date of Collection / Notification of Death:	Dec/29/2020
----	---	-------------

**Cause of Death**

2.a	Cause of Death Status:	PRIMARY CAUSE OF DEATH
	Cause of Death:	[Pneumonia due to COVID-19]

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Dec/26/2020

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** CASEBOOK SIGNATURE FORM

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Stephen Grubb	Approved	Mar-03-2021 12:07:11 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, StephenGrubb, 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:** 1252

**Subject No:** 12521010

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

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

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Aug-21-2020 06:21:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
2	Jan-06-2021 10:30:47 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable
			Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
3	Jan-06-2021 10:31:47 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 10-Dec-2020 02:28

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
5.a	Dec-31-2020 11:40:24 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Low and high levels not provided on report

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 10-Dec-2020 02:28

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
5.a	Dec-31-2020 11:40:24 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Low and high levels not provided on report

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 10-Dec-2020 02:28

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
5.a	Dec-31-2020 11:40:24 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Low and high levels not provided on report

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 10-Dec-2020 02:28

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
5.a	Dec-31-2020 11:40:24 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Low and high levels not provided on report

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 10-Dec-2020 02:28

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
5.b	Dec-31-2020 11:41:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Low and High levels not given on reports.



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 10-Dec-2020 02:28

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
5.b	Dec-31-2020 11:41:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Low and High levels not given on reports.

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 10-Dec-2020 02:28

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
5.b	Dec-31-2020 11:41:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Low and High levels not given on reports.

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 10-Dec-2020 02:28

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
5.b	Dec-31-2020 11:41:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Low and High levels not given on reports.

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments  
Dec/25/2020

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

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
Form	Jan-12-2021 09:46:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments  
Dec/25/2020

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

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
1	Jan-13-2021 08:14:42 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not applicable

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments  
Dec/25/2020

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

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
2.a	Jan-13-2021 08:15:20 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not applicable
2.a	Jan-13-2021 08:14:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments  
Dec/25/2020

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

**Form Status:** Data Complete, Deleted

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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

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Item	Date	User	Comment
Form	Jan-12-2021 09:48:55 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Comments  
Dec/25/2020

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

**Form Status:** Data Complete, Deleted

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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

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Item	Date	User	Comment
2.a	Jan-12-2021 09:47:23 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS - Comments  
Dec/25/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
Form	Dec-31-2020 12:37:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not applicable ----- Not Applicable

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS - Comments  
Dec/25/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
1	Dec-31-2020 12:37:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not applicable <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS - Comments  
Dec/25/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
2	Dec-31-2020 12:37:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable
			Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS - Comments  
Dec/25/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
3	Dec-31-2020 12:37:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not applicable <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments  
Dec/25/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
Form	Jan-08-2021 08:39:48 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	NOT APPLICABLE ----- Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments  
Dec/25/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
1	Jan-08-2021 08:39:48 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	NOT APPLICABLE <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments  
Dec/25/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
2	Jan-08-2021 08:39:48 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	NOT APPLICABLE ----- Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments  
Dec/25/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
3	Jan-08-2021 08:39:48 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	NOT APPLICABLE ----- Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments  
Dec/25/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
4	Jan-08-2021 08:39:48 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	NOT APPLICABLE Not Applicable
4	Jan-05-2021 08:23:06 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done Not Done
4	Dec-31-2020 12:22:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable Not Applicable

**Header Text:** c4591001

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

**Form Status:** Data Complete, Frozen

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**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
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**Generated By:** (b) (4)

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Item	Date	User	Comment
5	Jan-08-2021 08:39:48 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	NOT APPLICABLE Not Applicable
5	Jan-05-2021 08:24:29 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments  
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**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1252

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Item	Date	User	Comment
6	Jan-08-2021 08:39:48 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	NOT APPLICABLE _____ Not Applicable
6	Jan-05-2021 08:24:49 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Done _____ Not Done

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**Header Text:** c4591001

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**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
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**Subject No:** 12521010

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Jan-12-2021 09:46:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** IMAGING - Comments  
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**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
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**Generated By:** (b) (4)

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Item	Date	User	Comment
1	Jan-12-2021 09:48:17 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not applicable

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**Header Text:** c4591001

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2	Jan-12-2021 09:47:51 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** IMAGING - Comments  
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**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
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**Subject Initials:** ---

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Item	Date	User	Comment
3	Jan-12-2021 09:48:04 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not applicable

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

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**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
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**Subject No:** 12521010

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

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4	Jan-12-2021 09:48:32 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Dec/26/2020

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

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

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Feb-11-2021 08:31:25 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done Patient died on 26Dec2020 and Illness Convalescent Visit
Form	Feb-09-2021 09:51:19 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Patient died on 26Dec2020 and Illness Convalescent Visit not done

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**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1

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

**Site No:** 1252

**Subject No:** 12521010

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

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

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

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Item	Date	User	Comment
1	Feb-10-2021 15:18:25 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	There was no Convalescent visit for the subject passed away on 26Dec2020

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1

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

**Site No:** 1252

**Subject No:** 12521010

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

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

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

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2	Feb-11-2021 08:31:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not done

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**Visit:** POT\_COVID\_CONVA 1

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**Site No:** 1252

**Subject No:** 12521010

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

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

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**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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Item	Date	User	Comment
3	Feb-11-2021 08:32:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Dec/26/2020

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
Comments

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

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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Form	Feb-16-2021 10:06:38 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

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**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
Comments

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

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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Item	Date	User	Comment
1	Feb-16-2021 10:06:38 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
Comments

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

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Item	Date	User	Comment
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Item	Date	User	Comment
3	Feb-16-2021 10:06:38 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done



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

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Item	Date	User	Comment
4	Feb-16-2021 10:06:38 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Done

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** MEDICATION ERROR - Comments

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Dec-21-2020 11:23:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1252

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**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

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Item	Date	User	Comment
1	Dec-21-2020 11:23:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
2	Dec-21-2020 11:23:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
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**Generated By:** (b) (4)

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**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

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Item	Date	User	Comment
7	Dec-21-2020 11:23:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
8	Dec-21-2020 11:23:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
9	Dec-21-2020 11:23:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
10	Dec-21-2020 11:23:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
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**Form Version:** 22-Apr-2020 21:03

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
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**Subject No:** 12521010

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Dec-21-2020 13:29:47 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not applicable ----- Not Applicable
Form	Dec-21-2020 11:42:30 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not applicable

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Item	Date	User	Comment
1	Dec-21-2020 13:29:47 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable
			Not Applicable

**Header Text:** c4591001

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Item	Date	User	Comment
2	Dec-21-2020 13:29:47 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable
			Not Applicable

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

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3	Dec-21-2020 13:29:47 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable
			Not Applicable



**Header Text:** c4591001

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Item	Date	User	Comment
4	Dec-21-2020 13:29:47 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable
			Not Applicable
4	Dec-21-2020 11:30:48 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Wrong information

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
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5	Dec-21-2020 13:29:47 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not applicable <hr/> Not Applicable

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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Item	Date	User	Comment
Form	Dec-21-2020 13:30:34 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

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

**Site No:** 1252

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

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1	Dec-21-2020 13:30:34 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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

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2	Dec-21-2020 13:30:34 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [REDACTED]	Not Applicable

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
Form	Dec-21-2020 11:40:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
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**Header Text:** c4591001

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Item	Date	User	Comment
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Item	Date	User	Comment
4	Dec-21-2020 11:40:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
5	Dec-21-2020 11:40:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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Item	Date	User	Comment
6	Dec-21-2020 11:40:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
7	Dec-21-2020 11:40:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
8	Dec-21-2020 11:40:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
9	Dec-21-2020 11:40:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



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**Subject Initials:** ---

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10	Dec-21-2020 11:40:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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**Site No:** 1252

**Subject No:** 12521010

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

**Form:** RADIATION TREATMENT - Comments

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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Form	Dec-21-2020 11:41:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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1	Dec-21-2020 11:41:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
2	Dec-21-2020 11:41:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
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Form	Dec-21-2020 11:41:42 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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**Site No:** 1252

**Subject No:** 12521010

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

**Form:** TREATMENT UNBLINDED - Comments

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

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**Subject No:** 12521010

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

**Form:** WITHDRAWAL OF CONSENT - Comments

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Jan-05-2021 09:24:37 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable
			Not Applicable

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** Disposition

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** WITHDRAWAL OF CONSENT - Comments

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Jan-05-2021 09:24:37 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable
			Not Applicable



Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

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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
Stephen Grubb	Approved	Mar-03-2021 12:07:11 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, StephenGrubb, 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-25-2021 10:38:31 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Stephen Grubb	Approved	Feb-24-2021 16:20:25 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, StephenGrubb, 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-17-2021 09:40:00 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Stephen Grubb	Approved	Feb-16-2021 17:02:05 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (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:** 1252**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine**Subject No:** 12521010**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51**Affidavit:**

By my dated signature below, I, StephenGrubb, 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-15-2021 12:18:42 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Stephen Grubb	Approved	Feb-12-2021 14:22:47 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, StephenGrubb, 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-10-2021 15:10:38 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Stephen Grubb	Approved	Feb-09-2021 11:55:01 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, StephenGrubb, 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:** Investigator Signature - Unscheduled

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

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

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

(b) (6)	N/A	Feb-08-2021 13:36:45 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Stephen Grubb	Approved	Jan-29-2021 09:15:07 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Jan-26-2021 14:56:42 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Stephen Grubb	Approved	Jan-24-2021 13:47:34 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Jan-18-2021 08:21:35 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Stephen Grubb	Approved	Jan-15-2021 11:22:32 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (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:** 1252**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine**Subject No:** 12521010**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51**Affidavit:**

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

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

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

(b) (6)	N/A	Jan-12-2021 09:27:39 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Stephen Grubb	Approved	Jan-11-2021 17:03:14 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, StephenGrubb, 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-21-2020 13:29:47 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Stephen Grubb	Approved	Dec-21-2020 12:10:18 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, StephenGrubb, 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:** Investigator Signature - Unscheduled

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

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

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

(b) (6)	N/A	Dec-21-2020 11:23:21 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Stephen Grubb	Approved	Oct-21-2020 17:20:32 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, StephenGrubb, 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.

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** COHORT\_SELECTION - eCRF Audit Trail History

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Aug-17-2020 22:23:12 (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-17-2020 22:23:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

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*I. Consent Was:*

Date	Location	User	Value	Reason
Aug-17-2020 22:23:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Aug/17/2020	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1252

Subject No: 12521010

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject Initials: ---

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

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**1. Subject ID**

Date	Location	User	Value	Reason
Aug-17-2020 22:22:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12521010	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-17-2020 22:22:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1939	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-17-2020 22:23:43 (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-17-2020 22:23:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) O R OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-17-2020 22:23:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Aug-17-2020 22:24:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aug/17/2020	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

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**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Aug-21-2020 06:22:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/17/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-21-2020 06:22:34 (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-21-2020 06:22:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1252

Subject No: 12521010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject Initials: ---

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

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*I.a*

Date	Location	User	Value	Reason
Sep-02-2020 22:21:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History Term:</b> Hypertension <b>Start Date:</b> UNK/UNK/2018 <b>Ongoing:</b> YES	Initial Entry

*I.a Line/MH Number:*

Date	Location	User	Value	Reason
Sep-02-2020 22:21:59 (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
Sep-02-2020 22:21:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hypertension	Initial Entry

*I.a Start Date:*

Date	Location	User	Value	Reason
Sep-02-2020 22:21:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2018	Initial Entry

*I.a Ongoing:*

Date	Location	User	Value	Reason
Sep-02-2020 22:21:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

*I.b*

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1252

Subject No: 12521010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject Initials: ---

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

Date	Location	User	Value	Reason
Sep-02-2020 22:22:46 (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> Seasonal Allergies <b>Start Date:</b> Apr/18/2018 <b>Ongoing:</b> YES	Initial Entry

*I.b Line/MH Number:*

Date	Location	User	Value	Reason
Sep-02-2020 22:22:46 (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
Sep-02-2020 22:22:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Seasonal Allergies	Initial Entry

*I.b Start Date:*

Date	Location	User	Value	Reason
Sep-02-2020 22:22:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Apr/18/2018	Initial Entry

*I.b Ongoing:*

Date	Location	User	Value	Reason
Sep-02-2020 22:22:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

*I.c*

Date	Location	User	Value	Reason
Sep-02-2020 22:23:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 3 <b>Medical History Term:</b> Vertigo	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1252

Subject No: 12521010

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject Initials: ---

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

			<b>Start Date:</b>	Oct/2/2019	
			<b>Ongoing:</b>	YES	

**I.c Line/MH Number:**

Date	Location	User	Value	Reason
Sep-02-2020 22:23:50 (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
Sep-02-2020 22:23:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Vertigo	Initial Entry

**I.c Start Date:**

Date	Location	User	Value	Reason
Sep-02-2020 22:23:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/2/2019	Initial Entry

**I.c Ongoing:**

Date	Location	User	Value	Reason
Sep-02-2020 22:23:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1252

Subject No: 12521010

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject Initials: ---

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

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Aug-25-2020 18:30:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/17/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-25-2020 18:30:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 165.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-25-2020 18:30:11 (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-25-2020 18:30:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 63.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Aug-25-2020 18:30:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> in	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Aug-25-2020 18:30:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 29.2	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1252

Subject No: 12521010

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject Initials: ---

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

7.a

Date	Location	User	Value	Reason
Aug-25-2020 18:30:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 98.6 <b>Temperature Unit:</b> F <b>Temperature Location::</b> ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-25-2020 18:30:11 (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-25-2020 18:30:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.6	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-25-2020 18:30:11 (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-25-2020 18:30:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** RANDOMIZATION - eCRF Audit Trail History

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Aug-21-2020 06:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/17/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-21-2020 06:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 230749	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: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-21-2020 06:23:46 (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-21-2020 06:23:46 (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-21-2020 06:23:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-21-2020 06:23:46 (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-21-2020 06:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/17/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-21-2020 06:23:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BNWG1K	Initial Entry

**5.a Sample ID**

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Aug-21-2020 06:23:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BNWG1K	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-21-2020 06:24:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BNWG1L	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 06:24:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BNWG1L	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-21-2020 06:24:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPYXM0	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 06:24:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPYXM0	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-21-2020 06:24:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPYXM1	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

**5.d Sample ID**

Date	Location	User	Value	Reason
Aug-21-2020 06:24:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPYXM1	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Aug-21-2020 06:24:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPYXM2	Initial Entry

**5.e Sample ID**

Date	Location	User	Value	Reason
Aug-21-2020 06:24:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPYXM2	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-21-2020 06:25:27 (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-21-2020 06:25:27 (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-21-2020 06:25:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-21-2020 06:25:27 (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-21-2020 06:25:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/17/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-21-2020 06:25:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPYXLZ	Initial Entry

**5.a Sample ID**

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History

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

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Aug-21-2020 06:25:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPYXLZ	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1252

Subject No: 12521010

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject Initials: ---

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

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Aug-25-2020 18:46:14 (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-25-2020 18:46:14 (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-25-2020 18:46:14 (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-25-2020 18:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/17/2020 15:44	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-25-2020 18:46:14 (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-25-2020 18:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** VACCINATION - eCRF Audit Trail History

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

**7. Route:**

Date	Location	User	Value	Reason
Aug-25-2020 18:46:14 (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-25-2020 18:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBS ERVATION 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-25-2020 18:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 06-Jul-2020 21:53

Site No: 1252

Subject No: 12521010

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject Initials: ---

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

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Sep-21-2020 02:56:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Sep-18-2020 11:49:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	No e-diary collected for the subject
Sep-18-2020 04:22:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 2: Opened	eDiary: Per eDiary records, VAX 2 eDiary records are not available for the subject . Please confirm in query response appropriately. (b) (4)
Sep-07-2020 06:59:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-02-2020 22:10:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-02-2020 22:10:23 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES - R EACTO	Transcription Error

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

(US & Canada)			GENICITY E-DIARY COLLECTED FOR THIS SUBJECT	
Sep-02-2020 05:56:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	eDiary: REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT is 'No' however VAX 1 eDiary records are available for the subject. Please verify and update. Else, confirm in query response appropriately.
Aug-24-2020 21:08:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

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*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-08-2020 15:57:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/8/2020	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

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1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FAT IG UE	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
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2.b Symptom:

Date	Location	User	Value	Reason
Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HEA DAC HE  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:52**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1252**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine**Subject No:** 12521010**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51**2.c Symptom:**

Date	Location	User	Value	Reason
Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HEADACHE	Initial Entry

**2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.d**

Date	Location	User	Value	Reason
Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> CH ILL S  <b>Were fever or systemic sympt oms present on the last day th e Subject Diary was complete d?:</b> NO	Initial Entry

**2.d Symptom:**

Date	Location	User	Value	Reason
Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

**2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.e**

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b>  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry  VO MIT ING  NO
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2.e Symptom:

Date	Location	User	Value	Reason
Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b>  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry  DIA RR HE A  NO

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

Date	Location	User	Value	Reason
Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE ED MUSC LE PAIN  <b>Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:</b>	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE NED MUSCLE P AIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.h

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE ED JOINT PAIN  <b>Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:</b>	Initial Entry

**2.h Symptom:**

Date	Location	User	Value	Reason
Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE NED JOINT PAI N	Initial Entry

**2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**4. Injection Site Body Side:**

Date	Location	User	Value	Reason
Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)



Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RE DN ESS <b>Were injection site reactions NO present on the last day the Su bject Diary was completed?:</b>	Initial Entry
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**5.a Injection Site Reaction:**

Date	Location	User	Value	Reason
Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> REDNESS	Initial Entry

**5.a Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> SWE LLI NG <b>Were injection site reactions NO present on the last day the S ubject Diary was completed ?:</b>	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> PAIN AT INJECTION SITE  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-08-2020 15:59:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 21-Aug-2020 02:51

Site No: 1252

Subject No: 12521010

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject Initials: ---

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

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**I. Date:**

Date	Location	User	Value	Reason
Sep-08-2020 16:00:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/8/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-08-2020 16:00:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 98.3 <b>Temperature Unit:</b> F <b>Temperature Location::</b> ORAL CAVITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-08-2020 16:00:33 (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-08-2020 16:00:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.3	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-08-2020 16:00:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

Sep-08-2020 16:00:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry
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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: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-08-2020 16:01:51 (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
Sep-08-2020 16:01:51 (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-08-2020 16:02:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-08-2020 16:01:51 (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.
Sep-08-2020 16:01:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/8/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-08-2020 16:02:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPYXZK	Initial Entry

**5.a Sample ID**

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History

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

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

Date	Location	User	Value	Reason
Sep-08-2020 16:02:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPYXZK	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1252

Subject No: 12521010

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject Initials: ---

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

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-08-2020 16:04:55 (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-08-2020 16:04:55 (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-08-2020 16:04:55 (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-08-2020 16:04:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/8/2020 10:50	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-08-2020 16:04:55 (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-08-2020 16:04:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** VACCINATION - eCRF Audit Trail History

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

**7. Route:**

Date	Location	User	Value	Reason
Sep-08-2020 16:04:55 (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-08-2020 16:04:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBS ERVATION 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-08-2020 16:04:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)



**Header Text:** c4591001

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

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

**Site No:** 1252

**Subject No:** 12521010

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Oct-07-2020 07:04:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	As per site confirmation - updated PD tracker
Oct-06-2020 08:40:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Oct-06-2020 06:13:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	PDQ: DOV at this visit is out of window (-1 day) from DOV (08/Sep/2020) at V2_VAX2_L. Please reconcile and update accordingly, else confirm date is correct as is.
Oct-05-2020 14:58:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/5/2020	Transcription Error
Oct-05-2020 14:58:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/5/2020	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

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*1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?*

Date	Location	User	Value	Reason
Oct-05-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*2.a*

Date	Location	User	Value	Reason
Oct-05-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

*2.a Symptom:*

Date	Location	User	Value	Reason
Oct-05-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

*2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?*

Date	Location	User	Value	Reason
Oct-05-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*2.b*

Date	Location	User	Value	Reason
Oct-05-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FAT IG UE	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
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2.b Symptom:

Date	Location	User	Value	Reason
Oct-05-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-05-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Oct-05-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: HEA DAC HE  Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:52**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1252**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine**Subject No:** 12521010**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51**2.c Symptom:**

Date	Location	User	Value	Reason
Oct-05-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HEADACHE	Initial Entry

**2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-05-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.d**

Date	Location	User	Value	Reason
Oct-05-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> CH ILL S  <b>Were fever or systemic sympt oms present on the last day th e Subject Diary was complete d?:</b> NO	Initial Entry

**2.d Symptom:**

Date	Location	User	Value	Reason
Oct-05-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

**2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-05-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.e**

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

Oct-05-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b>  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry  VO MIT ING  NO
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2.e Symptom:

Date	Location	User	Value	Reason
Oct-05-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-05-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Oct-05-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b>  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry  DIA RR HE A  NO

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

2.f Symptom:

Date	Location	User	Value	Reason
Oct-05-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-05-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Oct-05-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE ED MUSC LE PAIN  <b>Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:</b>	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Oct-05-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE NED MUSCLE P AIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-05-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.h

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-05-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE ED JOINT PAIN  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

**2.h Symptom:**

Date	Location	User	Value	Reason
Oct-05-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE NED JOINT PAI N	Initial Entry

**2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-05-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
Oct-05-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**4. Injection Site Body Side:**

Date	Location	User	Value	Reason
Oct-05-2020 15:02:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

Oct-05-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RE DN ESS <b>Were injection site reactions NO</b> <b>present on the last day the Su</b> <b>bject Diary was completed?:</b>	Initial Entry
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**5.a Injection Site Reaction:**

Date	Location	User	Value	Reason
Oct-05-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> REDNESS	Initial Entry

**5.a Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-05-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Oct-05-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> SWE LLI NG <b>Were injection site reactions NO</b> <b>present on the last day the S</b> <b>ubject Diary was completed</b> <b>?:</b>	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)



Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-05-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-05-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-05-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> PAIN AT INJECTION SITE  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-05-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-05-2020 15:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (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: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-05-2020 15:03:49 (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-05-2020 15:03:49 (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-05-2020 15:04:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-05-2020 15:03:49 (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-05-2020 15:03:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/5/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-05-2020 15:04:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPYY1Y	Initial Entry

**5.a Sample ID**

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (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: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-05-2020 15:04:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPYY1Y	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-05-2020 15:04:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPYY1Z	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-05-2020 15:04:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPYY1Z	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-05-2020 15:04:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPYY20	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-05-2020 15:04:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPYY20	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-05-2020 15:05:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BNWG3X	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (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:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

**5.d Sample ID**

Date	Location	User	Value	Reason
Oct-05-2020 15:05:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNWG3X	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Oct-05-2020 15:05:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BNWG3Y	Initial Entry

**5.e Sample ID**

Date	Location	User	Value	Reason
Oct-05-2020 15:05:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BNWG3Y	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History Dec/25/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

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*I. Date of Visit*

Date	Location	User	Value	Reason
Jan-15-2021 03:20:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Jan-13-2021 08:25:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Original value is correct
Jan-12-2021 03:22:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Jan-11-2021 11:39:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: 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.
Jan-04-2021 08:20:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed as reason recorded on SWAB CRFs
Dec-31-2020 09:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The subject did not collect a Self Nasal Swab. The hospital did collect a Nasal Swab and used kit ABBOTT I NOW SARS-COV-2 POINT OF CARE on 25Dec2020 when he was admitted.
Dec-31-2020 05:23:52	ACV0PFEINFP6000	(b) (6)	Query 1: Opened	Date of Visit is

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History  
Dec/25/2020**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1252**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine**Subject No:** 12521010**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51

(UTC-05:00) Eastern Time (US & Canada)		(b) (4)		completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Dec-30-2020 17:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Dec-30-2020 17:04:09 (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-30-2020 17:04:09 (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-30-2020 17:04:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/25/2020	Initial Entry

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

Date	Location	User	Value	Reason
Dec-30-2020 17:04:09 (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 on Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF  
Dec/25/2020 Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Dec-30-2020 17:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/25/2020	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Dec-30-2020 17:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/25/2020	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Dec-30-2020 17:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Symptom Resolved: Dec/26/2020	Initial Entry

**4.a**

Date	Location	User	Value	Reason
Dec-30-2020 17:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms: FEVER Symptom Present: NO	Initial Entry

**4.a Symptoms:**

Date	Location	User	Value	Reason
Dec-30-2020 17:07:10 (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
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090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

Dec-30-2020 17:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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4.b

Date	Location	User	Value	Reason
Dec-30-2020 17:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASE D COUGH <b>Symptom P</b> NO <b>resent:</b>	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Dec-30-2020 17:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Dec-30-2020 17:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Dec-30-2020 17:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sympto</b> NEW OR INCREASED <b>ms:</b> SHORTNESS OF BREA TH <b>Sympto</b> YES <b>m Presen</b> <b>t:</b>	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

4.c Symptoms:

Date	Location	User	Value	Reason
Dec-30-2020 17:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SHORTNE SS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Dec-30-2020 17:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.d

Date	Location	User	Value	Reason
Dec-30-2020 17:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms: CHILLS Symptom Present: NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Dec-30-2020 17:07:10 (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-30-2020 17:07:10 (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-30-2020 17:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms : NEW OR INCREASE D MUSCLE PAIN	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF  
Dec/25/2020 Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

			Symptom NO Present:	
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4.e Symptoms:

Date	Location	User	Value	Reason
Dec-30-2020 17:07:10 (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-30-2020 17:07:10 (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-30-2020 17:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms: NEW LOSS OF TASTE OR SMELL Symptom P NO present:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Dec-30-2020 17:07:10 (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-30-2020 17:07:10 (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

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete**Site No:** 1252**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine**Subject No:** 12521010**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51

Dec-30-2020 17:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> NEW OR INCREASE : D SORE THROAT <b>Symptom</b> NO <b>Present:</b>	Initial Entry
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**4.g Symptoms:**

Date	Location	User	Value	Reason
Dec-30-2020 17:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SORE THR OAT	Initial Entry

**4.g Was symptom present?**

Date	Location	User	Value	Reason
Dec-30-2020 17:07:10 (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-30-2020 17:07:10 (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	Initial Entry

**4.h Symptoms:**

Date	Location	User	Value	Reason
Dec-30-2020 17:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

**4.h Was symptom present?**

Date	Location	User	Value	Reason
Dec-30-2020 17:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.i**

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF  
Dec/25/2020 Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Dec-30-2020 17:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITING <b>Symptom Present:</b> NO	Initial Entry

**4.i Symptoms:**

Date	Location	User	Value	Reason
Dec-30-2020 17:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

**4.i Was symptom present?**

Date	Location	User	Value	Reason
Dec-30-2020 17:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-30-2020 17:07:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms - Other:</b> Chest congestion	Initial Entry

**5.a Symptoms - Other Text:**

Date	Location	User	Value	Reason
Dec-30-2020 17:07:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Chest congestion	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Audit Trail  
Dec/25/2020

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

**Form Status:**

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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Date	Location	User	Value	Reason
Dec-30-2020 17:09:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History  
Dec/25/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Jan-04-2021 08:57:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-31-2020 09:12:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	#2,3 and 6 answered for query
Dec-31-2020 04:12:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Please complete item # 2, 3 and 6. Thank you.
Dec-30-2020 17:09:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/25/2020	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Dec-31-2020 09:09:54 (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-31-2020 09:09:54 (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-30-2020 17:09:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RESP SYNDRO ME CORONAVIRUS 2	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
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090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History  
Dec/25/2020

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

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

Dec-30-2020 17:09:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGNOSTIC TEST	Initial Entry
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**6. Trade Name:**

Date	Location	User	Value	Reason
Dec-31-2020 09:09:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ABBOTT DIAGNOSTICS ID NO W COVID-19	Initial Entry

**7. Test Result:**

Date	Location	User	Value	Reason
Dec-30-2020 17:09:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> POSITIVE	Initial Entry

**8. Comments/Findings/Details:**

Date	Location	User	Value	Reason
Dec-31-2020 09:09:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hospital reported that the nasal swab came back positive.	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1252**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine**Subject No:** 12521010**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-30-2020 17:09:30 (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-30-2020 17:09:30 (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-30-2020 17:21:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-30-2020 17:09:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Dec-30-2020 17:09:30 (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
Jan-12-2021 16:35:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Subject went to hospital emergency and never was able to do a SELF S	New Information



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

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

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

			WAB HOME KIT. The subject passed!	
Dec-30-2020 17:21:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Subject went to emergency department	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Dec/25/2020 Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Dec-30-2020 17:09:51 (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
Dec-30-2020 17:09:51 (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
Jan-12-2021 02:20:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-11-2021 11:39:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Answer Auto Query
Jan-11-2021 11:39:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Sample not collected in clinic or self swab. No barcode to record for swab completed in the ER dept.
Jan-11-2021 02:14:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM: If sampling done then Barcode must be recorded. Please verify and consider update data. Thank you.
Jan-08-2021 08:38:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	NASAL SWAB WAS COLLECTED AT THE HOSPITAL (IN HOUSE KIT) WHERE SUBJECT

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1252**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine**Subject No:** 12521010**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51

				WAS ADMITTED. THIS INFORMATION WAS GATHERED FROM THE SUBJECTS HOSPITAL MEDICAL RECORD. THERE IS NO BARCODE FOR TRACKING AVAILABLE.
Jan-08-2021 07:52:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-06-2021 08:11:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-06-2021 08:11:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Dec/25/2020	Transcription Error
Dec-30-2020 17:22:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-30-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Dec-30-2020 17:09:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Jan-13-2021 07:18:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed as data updated.
Jan-12-2021 16:40:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Hospital did a Nasal Swab when subject was admitted. The kit used was Abbott ID NOW SARS-COV-2 Point of care according to medical records. The site never collected a Nasal Swab or Self Swab kit from the subject. The subject passed.
Jan-12-2021 16:38:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hospital did a Nasal Swab when subject was admitted. The kit used was ABBOTT ID NOW SARS-COV-2 POINT OF CARE according to medical records. The site never collected a Nasal Swab or a Self Nasal swab.	New Information
Jan-12-2021 16:37:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Entered text has either a carriage return (line break) or extra spaces at the end of the text or between words. Please correct by removing all data in the field and re-enter without adding extra spaces or using enter or tab keys.
Jan-12-2021 16:37:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hospital did a Nasal Swab when subject was admitted. The kit used was ABBOTT ID NOW SARS-COV-2 POINT OF CARE according	New Information

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

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

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

			g to medical records. The site never collected a Nasal Swab or a Self Nasal swab.	
Jan-06-2021 08:13:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hospital did a Nasal Swab when subject was admitted. The kit used was ABBOTT ID NOW SARS-COV-2 POINT OF CARE	New Information
Dec-30-2020 17:22:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Patient went to Emergency Department	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History  
Dec/25/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

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*I.a*

Date	Location	User	Value	Reason
Dec-30-2020 17:12:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIAL IST <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

*I.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Dec-30-2020 17:12:57 (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-30-2020 17:12:57 (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-30-2020 17:12:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENCY ROOM <b>Occurrence of Visits or Contacts:</b> YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History  
Dec/25/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

**I.b Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Dec-30-2020 17:12:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

**I.b Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Dec-30-2020 17:12:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Number of Visits or Contacts:</i>  1	Initial Entry

**I.c**

Date	Location	User	Value	Reason
Dec-30-2020 17:12:57 (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

**I.c Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Dec-30-2020 17:12:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

**I.c Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Dec-30-2020 17:12:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**I.d**

Date	Location	User	Value	Reason
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090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
 Dec/25/2020  
**Form Version:** 10-Dec-2020 02:26 **Form Status:** Data Complete  
**Site No:** 1252 **Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
 Medicine  
**Subject No:** 12521010 **Subject Initials:** ---  
**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

Dec-30-2020 17:12:57 (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
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**1.d Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Dec-30-2020 17:12:57 (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-30-2020 17:12:57 (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-30-2020 17:12:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE C ONSULTATION <b>Occurrence of Vi sits or Contacts:</b> NO	Initial Entry

**1.e Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Dec-30-2020 17:12:57 (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-30-2020 17:12:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History  
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Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family  
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Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

*I.f*

Date	Location	User	Value	Reason
Dec-30-2020 17:12:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTHE R <b>Occurrence of Visits or Co ntacts:</b> NO	Initial Entry

*I.f Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Dec-30-2020 17:12:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

*I.f Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Dec-30-2020 17:12:57 (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
Dec-30-2020 17:12:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Has the subject been in intensive ca re due to potential COVID-19 illnes s?  NO	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** HOSPITALIZATION DETAILS - Audit Trail  
Dec/25/2020

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

**Form Status:**

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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Date	Location	User	Value	Reason
Dec-30-2020 17:13:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History  
Dec/25/2020

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Hospitalization Category:**

Date	Location	User	Value	Reason
Dec-30-2020 17:13:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> HOSPITALIZATION STATUS	Initial Entry

**2. Hospitalization Term:**

Date	Location	User	Value	Reason
Dec-30-2020 17:13:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HOSPITAL	Initial Entry

**3. Admission Date:**

Date	Location	User	Value	Reason
Dec-30-2020 17:13:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/25/2020	Initial Entry

**4. Ongoing?**

Date	Location	User	Value	Reason
Dec-30-2020 17:13:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Discharge Date:  Dec/26/2020	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - Audit Trail  
Dec/25/2020

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

**Form Status:**

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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Date	Location	User	Value	Reason
Dec-30-2020 17:15:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: RESPIRATORY TREATMENT - eCRF Audit Trail History  
Dec/25/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

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**1. What is the treatment Identifier?**

Date	Location	User	Value	Reason
Dec-30-2020 17:15:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**2. Concomitant Non-drug Treatment Pre-specified:**

Date	Location	User	Value	Reason
Dec-30-2020 17:15:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> YES	Initial Entry

**3. Treatment:**

Date	Location	User	Value	Reason
Dec-30-2020 17:15:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HIGH FLOW OXYGEN THERAPY	Initial Entry

**4. Treatment:**

Date	Location	User	Value	Reason
Dec-30-2020 17:15:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> HIGH FLOW OXYGEN THERAPY	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Dec-30-2020 17:15:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/26/2020	Initial Entry

**6. Ongoing?**

Date	Location	User	Value	Reason
Dec-30-2020 17:15:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History  
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**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

			Dec/26/2020	
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: ILLNESS DETAILS - eCRF Audit Trail History  
Dec/25/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Dec-30-2020 17:16:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID-19 ILLNESS	Initial Entry

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

Date	Location	User	Value	Reason
Jan-05-2021 09:25:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-05-2021 09:07:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Jan-05-2021 09:07:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnosis:</i>  Pneumonia due to Covid 19  Date of Diagnosis:  Dec/25/2020	New Information
Jan-04-2021 16:31:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical Query: COVID-19 diagnosis should be entered on this CRF as there was a local positive test and symptoms recorded. Please update.
Dec-30-2020 17:16:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnosis:</i>  Pneumonia  Date of Diagnosis:	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - eCRF Audit Trail History  
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**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

			Dec/25/2020	
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**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Dec-30-2020 17:16:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 5	Initial Entry



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE - Audit Trail  
Dec/25/2020

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

**Form Status:**

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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Date	Location	User	Value	Reason
Dec-30-2020 17:17:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History  
Dec/25/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Dec-30-2020 17:17:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE COVID-19 ILLNESS	Initial Entry

**2. Subcategory of Clinical Event:**

Date	Location	User	Value	Reason
Dec-30-2020 17:17:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SIGNIFICANT ACUTE RENAL D YSFUNCTION	Initial Entry

**3. Was a diagnosis obtained?**

Date	Location	User	Value	Reason
Dec-30-2020 17:17:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Diagnosis:</i>  Acute kidney disease  Start Date:  Dec/25/2020  Ongoing?:  NO  End Date:  Dec/26/2020	Initial Entry

**4. Toxicity Grade:**

Date	Location	User	Value	Reason
Dec-30-2020 17:17:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 5	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Audit Trail

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

**Form Status:**

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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Date	Location	User	Value	Reason
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> CLINICAL CHEMISTRY	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> McLeod Loris Hospital 3611 Mitchell Street Loris SC 29569	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Feb-16-2021 17:09:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-16-2021 08:26:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Labs entered for the day are abnormal.
Feb-11-2021 14:41:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Only the most abnormal record is expected to be entered per date. please check and update data as appropriate. Please reach out to CRA if assistance is required.
Feb-10-2021 15:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Feb-10-2021 02:06:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Lab sampling information recorded on same date 25DEC2020. Please verify and update

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

				only unique results, which are most abnormal. Thank you.
Feb-09-2021 09:52:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Feb-09-2021 07:22:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	Per completion guidelines, If multiple values were recorded on a single day, the most abnormal should be recorded, Please review the collection date 25Dec2020 and update as applicable. Else clarify.
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/25/2020	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLOOD	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined</b> 329 <b>Identifier:</b> <b>Test::</b> C Reactive Protein_PX329 <b>Result::</b> 24.7 <b>Not Done::</b>	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

			<b>Lab Normal Range:</b> <i>Low</i> 0.0  <i>High</i> 1.0  <i>Unit</i> mg/dL	
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5.a Sponsor ID:

Date	Location	User	Value	Reason
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 329	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C Reactive Protein_PX329	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 24.7	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0.0  <i>High</i> 1.0  <i>Unit</i> mg/dL	Initial Entry

5.b

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020

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Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 30 <b>Test::</b> Alanine Aminotransferase_PX30 <b>Result::</b> <b>Not Done::</b> NOT DONE <b>Lab Normal Range:</b>	Initial Entry

5.b Sponsor ID:

Date	Location	User	Value	Reason
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Alanine Aminotransferase_PX30	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 28 <b>Test::</b> Aspartate Aminotransferase_PX28 <b>Result::</b> <b>Not Done::</b> NOT DONE	Initial Entry

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Header Text: c4591001

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Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

			Lab Normal Range:	
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5.c Sponsor ID:

Date	Location	User	Value	Reason
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 28	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aspartate Aminotransferase_PX28	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

5.d

Date	Location	User	Value	Reason
Feb-10-2021 15:34:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Alkaline Phosphatase_PX35 <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range:</b>	Changed Information
Feb-10-2021 15:32:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Alkaline Phosphatase_PX35	Changed Information

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

			<b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 50  <i>High</i> 250  <i>Unit</i> U/L	
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 35 <b>Test::</b> Alkaline Phosphatase_PX35 <b>Result::</b> 207 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 50  <i>High</i> 250  <i>Unit</i> U/L	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sponsor ID:

Date	Location	User	Value	Reason
Feb-10-2021 15:32:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Changed Information
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 35	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Alkaline Phosphatase_PX35	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Feb-10-2021 15:32:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 207	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Feb-10-2021 15:34:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 50  <i>High</i> 250  <i>Unit</i>	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

			U/L	
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5.e

Date	Location	User	Value	Reason
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Bilirubin_P X21 <b>Result::</b> 1.8 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0.1  <i>High</i> 1.2  <i>Unit</i> mg/dL	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:49**Form Status:** Data Complete**Site No:** 1252**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine**Subject No:** 12521010**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 21	Initial Entry

**5.e Test:**

Date	Location	User	Value	Reason
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Bilirubin_PX21	Initial Entry

**5.e Result:**

Date	Location	User	Value	Reason
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1.8	Initial Entry

**5.e LNMT**

Date	Location	User	Value	Reason
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 0.1  <i>High</i> 1.2  <i>Unit</i> mg/dL	Initial Entry

**5.f**

Date	Location	User	Value	Reason
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Blood Urea Nitro gen_PX47 <b>Result::</b> 91	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

			<b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 9  <i>High</i> 20  <i>Unit</i> mg/dL	
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5.f Sponsor ID:

Date	Location	User	Value	Reason
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 47	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Blood Urea Nitrogen_PX47	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 91	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 9  <i>High</i> 20  <i>Unit</i> mg/dL	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

5.g

Date	Location	User	Value	Reason
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 48 <b>Test::</b> Creatinine_P X48 <b>Result::</b> 4.15 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0.66  <i>High</i> 1.25  <i>Unit</i> mg/dL	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

5.g Sponsor ID:

Date	Location	User	Value	Reason
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 48	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Creatinine_PX48	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4.15	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Dec-31-2020 13:00:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 0.66  <i>High</i> 1.25  <i>Unit</i> mg/dL	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Audit Trail

**Form Version:** 10-Dec-2020 02:24

**Form Status:**

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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

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Date	Location	User	Value	Reason
Feb-10-2021 15:48:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:24

Form Status: Incomplete, Data Complete, Deleted

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Feb-10-2021 15:46:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Jan-05-2021 09:47:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> CLINICAL CHEMISTRY	Initial Entry
Jan-05-2021 09:45:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> CLINICAL CHEMISTRY	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Feb-10-2021 15:48:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> McLeod Loris Hospital 3611 Mitchell Street Loris SC 29569	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Feb-11-2021 06:06:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-10-2021 15:46:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Feb-10-2021 15:46:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Feb-10-2021 15:46:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-10-2021 15:38:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Collection date is updated, but result is missing. Please correct or confirm.
Feb-10-2021 13:37:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Only the most abnormal record is expected to be entered per date. please check and update data as appropriate. Please reach out to CRA if assistance is required.
Feb-09-2021 09:07:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Feb-09-2021 07:23:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	Per completion guidelines, If multiple values were recorded on a single day, the most abnormal should be recorded, Please review the collection date 25Dec2020 and update as applicable. Else clarify.
Jan-05-2021 09:47:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/25/2020	Initial Entry
Jan-05-2021 09:45:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/25/2020	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Feb-10-2021 15:46:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Jan-05-2021 09:47:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLOOD	Initial Entry

Jan-05-2021 09:45:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLOOD	Initial Entry
<b>5.a</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Feb-10-2021 15:36:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> C Reactive Prot ein_PX329 <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Ra nge:</b>	Changed Information
Feb-10-2021 15:36:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Define d Identifier:</b> <b>Test::</b> C Reactive Prot ein_PX329 <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Ra</b> <i>Low</i> <b>nge:</b> 0.0  <i>High</i> 1.0  <i>Unit</i> mg/dL	Changed Information
Jan-05-2021 09:47:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Define</b> 329 <b>d Identifier:</b> <b>Test::</b> C Reactive Prot ein_PX329 <b>Result::</b> 24.7 <b>Not Done::</b> <b>Lab Normal Ra</b> <i>Low</i> <b>nge:</b> 0.0  <i>High</i> 1.0  <i>Unit</i> mg/dL	Initial Entry

Jan-05-2021 09:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> C Reactive Prot ein_PX329 <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range:</b>	Transcription Error
Jan-05-2021 09:43:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> C Reactive Prot ein_PX329 <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0.0  <i>High</i> 1.0  <i>Unit</i> mg/dL	Transcription Error
Jan-05-2021 09:42:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 329 <b>Test::</b> C Reactive Prot ein_PX329 <b>Result::</b> 24.7 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0.0  <i>High</i> 1.0  <i>Unit</i> mg/dL	New Information
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 329 <b>Test::</b> C Reactive Prot ein_PX329 <b>Result::</b> 24.7 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Unit</i> mg/dL	Initial Entry

<b>5.a Sponsor ID:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Feb-10-2021 15:36:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Changed Information
Jan-05-2021 09:47:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 329	Initial Entry
Jan-05-2021 09:43:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 329	Initial Entry
<b>5.a Test:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C Reactive Protein_PX329	Initial Entry
<b>5.a Result:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Feb-10-2021 15:36:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Jan-05-2021 09:47:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 24.7	Initial Entry
Jan-05-2021 09:43:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Jan-05-2021 00:37:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-04-2021 08:11:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Jan-04-2021 06:18:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Thank you for the response. Please consider to update the ranges with available unit from the CRF options. Kindly connect with your CRA for any

				further assistance if needed.
Dec-31-2020 12:03:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Low and High range not provided
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 24.7	Initial Entry

**5.a LNMT**

Date	Location	User	Value	Reason
Feb-10-2021 15:36:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Jan-05-2021 09:47:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0.0  <i>High</i> 1.0  <i>Unit</i> mg/dL	Initial Entry
Jan-05-2021 09:45:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Jan-05-2021 09:42:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0.0  <i>High</i> 1.0  <i>Unit</i> mg/dL	New Information
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Unit</i> mg/dL	Initial Entry

**5.b**

Date	Location	User	Value	Reason
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Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Define d Identifier:</b> 30 <b>Test::</b> Alanine Aminotransferase_PX30 <b>Result::</b> <b>Not Done::</b> NOT DONE <b>Lab Normal Range:</b>	Initial Entry
<b>5.b Sponsor ID:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30	Initial Entry
<b>5.b Test:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Alanine Aminotransferase_PX30	Initial Entry
<b>5.b Not Done:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry
<b>5.c</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Define d Identifier:</b> 28 <b>Test::</b> Aspartate Aminotransferase_PX28 <b>Result::</b> <b>Not Done::</b> NOT DONE <b>Lab Normal Range:</b>	Initial Entry

<b>5.c Sponsor ID:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 28	Initial Entry
<b>5.c Test:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aspartate Aminotransferase_PX28	Initial Entry
<b>5.c Not Done:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry
<b>5.d</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Feb-10-2021 15:40:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Alkaline Phosph atase_PX35 <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range:</b>	Changed Information
Feb-10-2021 15:38:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Alkaline Phosph atase_PX35 <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 37  <i>High</i> 147  <i>Unit</i> U/L	Transcription Error
Jan-05-2021 08:44:49 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (6)	<b>Data Entry:</b>	New Information



<p>Time (US &amp; Canada)</p>		<p>(b) (4)</p>	<p><b>Sponsor-Defined Identifier:</b> 35  <b>Test::</b> Alkaline Phosphatase_PX35  <b>Result::</b> 207  <b>Not Done::</b>  <b>Lab Normal Range:</b> <i>Low</i> 37  <i>High</i> 147  <i>Unit</i> U/L</p>	
<p>Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US &amp; Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>auto calc (autocalc)</p>	<p><b>Data Entry:</b>  <b>Sponsor-Defined Identifier:</b> 35  <b>Test::</b> Alkaline Phosphatase_PX35  <b>Result::</b> 207  <b>Not Done::</b>  <b>Lab Normal Range:</b> <i>Unit</i> U/L</p>	<p>Initial Entry</p>

<b>5.d Sponsor ID:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Feb-10-2021 15:38:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 35	Initial Entry

<b>5.d Test:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Alkaline Phosphatase_PX35	Initial Entry

<b>5.d Result:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Feb-10-2021 15:38:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Jan-03-2021 23:50:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-31-2020 12:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Low and High range not provided
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 207	Initial Entry

<b>5.d LNMT</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Feb-10-2021 15:40:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Jan-05-2021 08:44:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 37 <i>High</i>	New Information

			147 <i>Unit</i> U/L	
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Unit</i> U/L	Initial Entry

5.e

Date	Location	User	Value	Reason
Feb-10-2021 15:39:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Bilirubin_P X21 <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range:</b>	Changed Information

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:24

Form Status: Incomplete, Data Complete, Deleted

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

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

[Back to Form](#)

5.e

Date	Location	User	Value	Reason
Feb-10-2021 15:35:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Bilirubin_P X21  <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0.1  <i>High</i> 1.5  <i>Unit</i> mg/dL	Changed Information
Jan-05-2021 08:40:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 21 <b>Test::</b> Bilirubin_P X21  <b>Result::</b> 1.8 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0.1  <i>High</i> 1.5  <i>Unit</i> mg/dL	Initial Entry
Jan-05-2021 08:40:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Bilirubin_P X21  <b>Result::</b>	New Information

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

			<b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0.1  <i>High</i> 1.5  <i>Unit</i> mg/dL	
Jan-05-2021 08:38:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Id entifier:</b> <b>Test::</b> Bilirubin_P X21  <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Unit</i> mg/dL	Transcription Error
Jan-05-2021 08:35:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Id 21 entifier:</b> <b>Test::</b> Bilirubin_P X21  <b>Result::</b> 1.8 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Unit</i> mg/dL	0.1-1.5 High
Jan-05-2021 08:33:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Id 21 entifier:</b> <b>Test::</b> Bilirubin_P X21  <b>Result::</b> 1.8 mg/dl <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Unit</i> mg/dL	High
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Id 21 entifier:</b> <b>Test::</b> Bilirubin_P X21  <b>Result::</b> 1.8 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Unit</i> mg/dL	Initial Entry

<b>5.e Sponsor ID:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Feb-10-2021 15:35:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Changed Information
Jan-05-2021 08:40:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 21	Initial Entry
Jan-05-2021 08:38:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 21	Initial Entry
<b>5.e Test:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Bilirubin_PX21	Initial Entry
<b>5.e Result:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Feb-10-2021 15:35:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Jan-05-2021 08:40:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1.8	Initial Entry
Jan-05-2021 08:38:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-05-2021 08:38:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Jan-05-2021 08:35:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1.8	0.1-1.5 High
Jan-05-2021 08:33:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Jan-05-2021 08:33:39 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1.8 mg/dl	High

Time (US & Canada)				
Jan-05-2021 01:43:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM2: Please update ranges or else clarify with the comment. Thank you.
Jan-04-2021 08:11:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Jan-04-2021 06:15:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Thank you for the response. Please consider to update the ranges with available unit from the CRF options. Kindly connect with your CRA for any further assistance if needed.
Dec-31-2020 12:04:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Low and High range not provided
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1.8	Initial Entry
<b>5.e LNMT</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Feb-10-2021 15:39:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Jan-05-2021 08:40:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0.1  <i>High</i> 1.5  <i>Unit</i> mg/dL	New Information
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Unit</i> mg/dL	Initial Entry

5.f				
Date	Location	User	Value	Reason
Feb-10-2021 15:39:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Blood Urea Nitrogen_PX47 <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range:</b>	Changed Information
Feb-10-2021 15:37:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Blood Urea Nitrogen_PX47 <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 5  <i>High</i> 20  <i>Unit</i> mg/dL	Changed Information
Jan-05-2021 08:42:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 47 <b>Test::</b> Blood Urea Nitrogen_PX47 <b>Result::</b> 91 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 5  <i>High</i> 20  <i>Unit</i> mg/dL	New Information
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 47 <b>Test::</b> Blood Urea Nitrogen_PX47 <b>Result::</b> 91 <b>Not Done::</b>	Initial Entry



		Lab Normal Range:	Unit	
			mg/dL	

<b>5.f Sponsor ID:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Feb-10-2021 15:37:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Changed Information
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 47	Initial Entry
<b>5.f Test:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Blood Urea Nitrogen_PX47	Initial Entry
<b>5.f Result:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Feb-10-2021 15:37:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Jan-05-2021 23:53:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-05-2021 08:42:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query
Jan-05-2021 02:55:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: If result is entered, the Lab normal range (Low, high or Unit) is required. Please contact Lab for correct normal ranges and update as appropriate. Thank you.
Jan-04-2021 08:12:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Jan-04-2021 06:15:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Thank you for the response. Please consider to update the ranges with available unit from the CRF options. Kindly connect with your CRA for any

				further assistance if needed.
Dec-31-2020 12:04:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Low and High range not provided
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 91	Initial Entry

**5.f LNMT**

Date	Location	User	Value	Reason
Feb-10-2021 15:39:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Jan-05-2021 08:42:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 5  <i>High</i> 20  <i>Unit</i> mg/dL	New Information
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Unit</i> mg/dL	Initial Entry

**5.g**

Date	Location	User	Value	Reason
Feb-10-2021 15:40:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Creatinine_PX48  <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range:</b> :	Changed Information
Feb-10-2021 15:38:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b>	Changed Information

			<p><b>Test::</b> Creatinine_P X48</p> <p><b>Result::</b></p> <p><b>Not Done::</b></p> <p><b>Lab Normal Range</b> <i>Low</i> : 0.3</p> <p><i>High</i> 1.5</p> <p><i>Unit</i> mg/dL</p>	
Jan-05-2021 08:43:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p><b>Sponsor-Defined Identifier:</b> 48</p> <p><b>Test::</b> Creatinine_P X48</p> <p><b>Result::</b> 4.15</p> <p><b>Not Done::</b></p> <p><b>Lab Normal Range</b> <i>Low</i> : 0.3</p> <p><i>High</i> 1.5</p> <p><i>Unit</i> mg/dL</p>	New Information

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:24

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

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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

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5.g

Date	Location	User	Value	Reason
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 48 <b>Test::</b> Creatinine_P X48 <b>Result::</b> 4.15 <b>Not Done::</b> <b>Lab Normal Range:</b> Unit mg/dL	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

<b>5.g Sponsor ID:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Feb-10-2021 15:38:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Changed Information
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 48	Initial Entry
<b>5.g Test:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Creatinine_PX48	Initial Entry
<b>5.g Result:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Feb-10-2021 15:38:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Jan-05-2021 23:52:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-04-2021 08:12:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Jan-04-2021 06:15:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Thank you for the response. Please consider to update the ranges with available unit from the CRF options. Kindly connect with your CRA for any further assistance if needed.
Dec-31-2020 12:05:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Low and High range not provided
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4.15	Initial Entry

<i>5.g LNMT</i>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Feb-10-2021 15:40:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Jan-05-2021 08:43:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 0.3  <i>High</i> 1.5  <i>Unit</i> mg/dL	New Information
Dec-31-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Unit</i> mg/dL	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Audit Trail

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

**Form Status:**

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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Date	Location	User	Value	Reason
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-06-2021 10:29:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> HEMATOLOGY	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Jan-06-2021 10:30:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Jan-06-2021 10:29:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> McLeod Loris Hospital 3611 Mitchell Street Loris SC 29569	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Jan-06-2021 10:31:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Jan-06-2021 10:29:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/25/2020	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
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090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

Jan-06-2021 10:29:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLOOD	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-06-2021 10:25:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Hemoglobin _PX1 <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range</b> :	Transcription Error
Jan-06-2021 10:24:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Hemoglobin _PX1 <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range</b> <i>Low</i> : 14.0  <i>High</i> 18.0  <i>Unit</i> g/dL	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier 1</b> <b>Test::</b> Hemoglobin _PX1 <b>Result::</b> 9.2	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

			<b>Not Done::</b> <b>Lab Normal Range</b> <i>Low</i> : 14.0  <i>High</i> 18.0  <i>Unit</i> g/dL	
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5.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-06-2021 10:24:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hemoglobin_PX1	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Jan-06-2021 10:24:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 9.2	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Jan-06-2021 10:25:07 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (6)	<b>Data Entry:</b>	Transcription Error

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)		(b) (4)		
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 14.0  <i>High</i> 18.0  <i>Unit</i> g/dL	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-06-2021 10:25:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Hematocrit_PX2  <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range:</b>	Transcription Error
Jan-06-2021 10:25:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Hematocrit_PX2  <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range</b> <i>Low</i> : 40.0  <i>High</i> 52.0  <i>Unit</i> %	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Id</b> 2	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

Time (US & Canada)			<b>entifier:</b>	
			<b>Test::</b>	Hematocrit_ PX2
			<b>Result::</b>	27.6
			<b>Not Done::</b>	
			<b>Lab Normal Range</b>	<i>Low</i>
			:	40.0
				<i>High</i>
				52.0
				<i>Unit</i>
				%

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sponsor ID:

Date	Location	User	Value	Reason
Jan-06-2021 10:25:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hematocrit_PX2	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Jan-06-2021 10:25:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 27.6	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Jan-06-2021 10:25:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 40.0  <i>High</i> 52.0  <i>Unit</i>	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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5.c

Date	Location	User	Value	Reason
Jan-06-2021 10:28:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Erythrocytes _PX3 <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range:</b>	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Erythrocytes _PX3 <b>Result::</b> <b>Not Done::</b> NOT DONE <b>Lab Normal Range:</b>	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sponsor ID:

Date	Location	User	Value	Reason
Jan-06-2021 10:28:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Erythrocytes_PX3	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Jan-06-2021 10:28:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-06-2021 10:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Platelets_P X5 <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range:</b>	Transcription Error
Jan-06-2021 10:25:45	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Transcription Error

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

(UTC-05:00) Eastern Time (US & Canada)		(autocalc)	<b>Sponsor-Defined Identifier:</b> <b>Test::</b> Platelets_P X5 <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 150  <i>High</i> 450  <i>Unit</i> /uL	
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 5 <b>Test::</b> Platelets_P X5 <b>Result::</b> 125 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 150  <i>High</i> 450  <i>Unit</i> /uL	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF  
Dec/25/2020 Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sponsor ID:

Date	Location	User	Value	Reason
Jan-06-2021 10:25:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Platelets_PX5	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Jan-06-2021 10:25:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 125	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Jan-06-2021 10:25:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 150  <i>High</i> 450  <i>Unit</i>	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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5.e

Date	Location	User	Value	Reason
Jan-06-2021 10:26:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Leukocytes_PX7 <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range:</b>	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 7 <b>Test::</b> Leukocytes_PX7 <b>Result::</b> <b>Not Done::</b> NOT DONE <b>Lab Normal Range:</b>	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:51**Form Status:** Data Complete, Frozen**Site No:** 1252**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine**Subject No:** 12521010**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Jan-06-2021 10:26:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

**5.e Test:**

Date	Location	User	Value	Reason
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Leukocytes_PX7	Initial Entry

**5.e Not Done:**

Date	Location	User	Value	Reason
Jan-06-2021 10:26:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

**5.f**

Date	Location	User	Value	Reason
Jan-06-2021 10:26:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Neutrophils_PX608 <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range:</b>	Transcription Error
Jan-06-2021 10:26:31	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Transcription Error

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

(UTC-05:00) Eastern Time (US & Canada)		(autocalc)	<b>Sponsor-Defined Identifier:</b> <b>Test::</b> Neutrophils_PX608 <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 40.0 <i>High</i> 64.0 <i>Unit</i> 10 <sup>9</sup> /L	
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 608 <b>Test::</b> Neutrophils_PX608 <b>Result::</b> 82.3 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 40.0 <i>High</i> 64.0 <i>Unit</i> 10 <sup>9</sup> /L	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

**5.f Sponsor ID:**

Date	Location	User	Value	Reason
Jan-06-2021 10:26:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 608	Initial Entry

**5.f Test:**

Date	Location	User	Value	Reason
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Neutrophils_PX608	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020

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Form Status: Data Complete, Frozen

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

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5.f Result:

Date	Location	User	Value	Reason
Jan-06-2021 10:26:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 82.3	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Jan-06-2021 10:26:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 40.0 <i>High</i> 64.0 <i>Unit</i> 10^9/L	Initial Entry

5.g

Date	Location	User	Value	Reason
Jan-06-2021 10:27:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Eosinophils_PX609 <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range:</b>	Transcription Error

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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**Form Status:** Data Complete, Frozen

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

Jan-06-2021 10:26:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Eosinophils_ PX609 <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0.00 <i>High</i> 0.50 <i>Unit</i> 10^9/L	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 609 <b>Test::</b> Eosinophils_ PX609 <b>Result::</b> 0.3 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0.00 <i>High</i> 0.50 <i>Unit</i> 10^9/L	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

5.g Sponsor ID:

Date	Location	User	Value	Reason
Jan-06-2021 10:26:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 609	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Eosinophils_PX609	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Jan-06-2021 10:26:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0.3	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Jan-06-2021 10:27:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0.00  <i>High</i> 0.50  <i>Unit</i>	Initial Entry

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Header Text: c4591001

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Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

			10^9/L	
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5.h

Date	Location	User	Value	Reason
Jan-06-2021 10:27:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Monocytes_P X612 <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range:</b>	Transcription Error
Jan-06-2021 10:27:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Monocytes_P X612 <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 4.0  <i>High</i> 10.0  <i>Unit</i> 10^9/L	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 612 <b>Test::</b> Monocytes_P X612 <b>Result::</b> 7.9 <b>Not Done::</b>	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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**Form Status:** Data Complete, Frozen

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

			<b>Lab Normal Range:</b>	
			<i>Low</i>	
			4.0	
			<i>High</i>	
			10.0	
			<i>Unit</i>	
			10 <sup>9</sup> /L	

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF  
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Form Status: Data Complete, Frozen

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

5.h Sponsor ID:

Date	Location	User	Value	Reason
Jan-06-2021 10:27:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 612	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Monocytes_PX612	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Jan-06-2021 10:27:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 7.9	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Jan-06-2021 10:27:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 4.0  <i>High</i> 10.0  <i>Unit</i>	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

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Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

			10^9/L	
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5.i

Date	Location	User	Value	Reason
Jan-06-2021 10:27:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Basophils_P X610 <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range</b> :	Transcription Error
Jan-06-2021 10:27:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Basophils_P X610 <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range</b> <i>Low</i> : 0.0  <i>High</i> 1.0  <i>Unit</i> 10^9/L	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 610 <b>Test::</b> Basophils_P X610 <b>Result::</b> 0.2 <b>Not Done::</b>	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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**Form Status:** Data Complete, Frozen

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

			<b>Lab Normal Range</b>	
			<i>Low</i>	
			:	0.0
			<i>High</i>	
				1.0
			<i>Unit</i>	
				10 <sup>9</sup> /L

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

5.i Sponsor ID:

Date	Location	User	Value	Reason
Jan-06-2021 10:27:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 610	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Basophils_PX610	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Jan-06-2021 10:27:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0.2	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Jan-06-2021 10:27:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0.0  <i>High</i> 1.0  <i>Unit</i>	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

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5.j

Date	Location	User	Value	Reason
Jan-06-2021 10:28:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Test:: Lymphocytes _PX611 <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range:</b>	Transcription Error
Jan-06-2021 10:28:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Test:: Lymphocytes_ PX611 <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range</b> <i>Low</i> e: 22.0  <i>High</i> 44.0  <i>Unit</i> 10^9/L	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 611 Test:: Lymphocytes_ PX611 <b>Result::</b> 8.8 <b>Not Done::</b>	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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**Form Status:** Data Complete, Frozen

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

			<b>Lab Normal Range</b>	
			<i>Low</i>	
			<b>e:</b>	22.0
			<i>High</i>	
				44.0
			<i>Unit</i>	
				10 <sup>9</sup> /L

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

5.j Sponsor ID:

Date	Location	User	Value	Reason
Jan-06-2021 10:28:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 611	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Lymphocytes_PX611	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Jan-06-2021 10:28:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 8.8	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Jan-06-2021 10:28:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Jan-05-2021 09:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 22.0  <i>High</i> 44.0  <i>Unit</i>	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Audit Trail

**Form Version:** 10-Dec-2020 02:28

**Form Status:**

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

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

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

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Date	Location	User	Value	Reason
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:28

Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Dec-31-2020 11:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> HEMATOLOGY	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Dec-31-2020 11:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> McLeod Loris Hospital 3611 Mitchell Street Loris SC 29569	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Dec-31-2020 11:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/25/2020	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Dec-31-2020 11:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLOOD	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-31-2020 13:15:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined Identifier: Test:: Hemoglobin _PX1 Result:: 9.2 Not Done::	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:28**Form Status:** Data Complete**Site No:** 1252**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine**Subject No:** 12521010**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51

			<b>Lab Normal Range</b> <i>Low</i> : 14.0  <i>High</i> 18.0  <i>Unit</i> g/dL	
Dec-31-2020 11:37:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Id 1</b> <b>entifier:</b> <b>Test::</b> Hemoglobin _PX1 <b>Result::</b> 9.2 <b>Not Done::</b> <b>Lab Normal Range</b> :	Transcription Error
Dec-31-2020 11:36:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Id 1</b> <b>entifier:</b> <b>Test::</b> Hemoglobin _PX1 <b>Result::</b> 6.9 <b>Not Done::</b> <b>Lab Normal Range</b> :	Transcription Error
Dec-31-2020 11:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Id 1</b> <b>entifier:</b> <b>Test::</b> Hemoglobin _PX1 <b>Result::</b> 6.9 <b>Not Done::</b> <b>Lab Normal Range</b> <i>Low</i> : Yes	Initial Entry
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Id 1</b> <b>entifier:</b> <b>Test::</b> Hemoglobin _PX1	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:28

Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			Result:: 6.9	
			Not Done::	
			Lab Normal Range	
			:	

5.a Sponsor ID:

Date	Location	User	Value	Reason
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hemoglobin_PX1	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Jan-03-2021 23:47:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Dec-31-2020 11:42:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Low and High range not given on report
Dec-31-2020 11:37:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 9.2	Transcription Error
Dec-31-2020 11:36:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-31-2020 11:36:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-31-2020 11:02:54 (UTC-05:00) Eastern	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:28

Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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Time (US & Canada)				(Low, high or Unit) is missing. Please correct or confirm.
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 6.9	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Dec-31-2020 13:15:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 14.0  <i>High</i> 18.0  <i>Unit</i> g/dL	Initial Entry
Dec-31-2020 11:36:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-31-2020 11:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> Yes	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-05-2021 08:47:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Hematocrit_PX2 <b>Result::</b> 27.6 <b>Not Done::</b>	New Information

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Header Text: c4591001

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Form Status: Data Complete

Site No: 1252

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Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			<b>Lab Normal Range</b> <i>Low</i> : 40.0  <i>High</i> 52.0  <i>Unit</i> %	
Dec-31-2020 13:15:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Id 2</b> <b>entifier:</b> <b>Test::</b> Hematocrit_ PX2 <b>Result::</b> 27.6 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 42.0  <i>High</i> 52.0	Initial Entry
Dec-31-2020 11:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Id 2</b> <b>entifier:</b> <b>Test::</b> Hematocrit_ PX2 <b>Result::</b> 27.6 <b>Not Done::</b> <b>Lab Normal Range:</b>	Transcription Error
Dec-31-2020 11:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Id 2</b> <b>entifier:</b> <b>Test::</b> Hematocrit_ PX2 <b>Result::</b> 27.6 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> Yes	Initial Entry
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Id 2</b> <b>entifier:</b>	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:28

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

			<b>Test::</b>	Hematocrit_	
				PX2	
			<b>Result::</b>	27.6	
			<b>Not Done::</b>		
			<b>Lab Normal Range:</b>		

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:28

Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.b Sponsor ID:

Date	Location	User	Value	Reason
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hematocrit_PX2	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Jan-06-2021 01:05:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Jan-05-2021 08:47:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Answer Auto Query
Jan-04-2021 23:56:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	DM: Please update Unit in Lab Normal Range field. Else, clarify.
Jan-04-2021 08:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Original value is correct
Jan-04-2021 01:21:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Closing as Low and High ranges are updated
Jan-04-2021 01:19:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	DM: Unit is still missing. Please correct or confirm
Dec-31-2020 13:16:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Low and High range submitted

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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:28**Form Status:** Data Complete**Site No:** 1252**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine**Subject No:** 12521010**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51

Dec-31-2020 13:15:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-31-2020 11:42:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Low and High range not given on report
Dec-31-2020 11:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-31-2020 11:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 27.6	Initial Entry

**5.b LNMT**

Date	Location	User	Value	Reason
Jan-05-2021 08:47:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 40.0  <i>High</i> 52.0  <i>Unit</i> %	New Information
Dec-31-2020 13:15:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 42.0  <i>High</i>	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF  
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Form Version: 10-Dec-2020 02:28

Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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			52.0	
Dec-31-2020 11:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-31-2020 11:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Low Yes	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 3 <b>Test::</b> Erythrocytes_ PX3 <b>Result::</b> <b>Not Done::</b> NOT DONE <b>Lab Normal Range:</b>	Initial Entry

5.c Sponsor ID:

Date	Location	User	Value	Reason
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Erythrocytes_PX3	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Dec-31-2020 11:02:54 (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 on Dec/25/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:28

Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.d

Date	Location	User	Value	Reason
Jan-05-2021 08:48:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 5 <b>Test::</b> Platelets_P X5 <b>Result::</b> 125 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 150  <i>High</i> 450  <i>Unit</i> /uL	New Information
Dec-31-2020 13:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 5 <b>Test::</b> Platelets_P X5 <b>Result::</b> 125 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 150  <i>High</i> 450	New Information
Dec-31-2020 11:34:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 5 <b>Test::</b> Platelets_P X5 <b>Result::</b> 125 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0  <i>High</i> 10.3	Transcription Error

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

**Generated By:** (b) (4)

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Dec-31-2020 11:32:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 5 <b>Test::</b> Platelets_P X5 <b>Result::</b> 125 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 82 <i>High</i> 88	Transcription Error
Dec-31-2020 11:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 5 <b>Test::</b> Platelets_P X5 <b>Result::</b> 125 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> Yes	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:28

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

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5.d

Date	Location	User	Value	Reason
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Platelets_P X5 <b>Result::</b> 125 <b>Not Done::</b> <b>Lab Normal Range:</b>	Initial Entry



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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5.d Sponsor ID:

Date	Location	User	Value	Reason
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 5	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Platelets_PX5	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Jan-06-2021 01:05:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-05-2021 08:48:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Answer Auto Query
Jan-05-2021 01:12:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM: Please update Unit in Lab Normal Range field. Else, clarify.
Jan-04-2021 08:15:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Original value is correct
Jan-04-2021 01:23:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-04-2021 01:23:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM: Unit is still missing. Please consider to update. Else; clarify.
Dec-31-2020 13:06:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Low and High range admitted

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

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Form Version: 10-Dec-2020 02:28

Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Dec-31-2020 13:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-31-2020 11:44:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Low and High range submitted
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 125	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Jan-05-2021 08:48:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 150  <i>High</i> 450  <i>Unit</i> /uL	New Information
Dec-31-2020 13:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 150  <i>High</i> 450	New Information
Dec-31-2020 11:34:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0  <i>High</i> 10.3	Transcription Error

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF  
Dec/25/2020 Audit Trail History

Form Version: 10-Dec-2020 02:28

Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Dec-31-2020 11:32:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Low 82  High 88	Transcription Error
Dec-31-2020 11:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Low Yes	Initial Entry

5.e

Date	Location	User	Value	Reason
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Defined Identifier: 7 Test:: Leukocytes_ PX7 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

5.e Sponsor ID:

Date	Location	User	Value	Reason
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Leukocytes_PX7	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Dec-31-2020 11:02:54 (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 on Dec/25/2020

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Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

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5.f

Date	Location	User	Value	Reason
Jan-06-2021 10:09:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 608 <b>Test::</b> Neutrophils_PX608 <b>Result::</b> 5.4 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 1.9 <i>High</i> 7.6 <i>Unit</i> 10 <sup>9</sup> /L	New Information
Jan-06-2021 10:08:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 608 <b>Test::</b> Neutrophils_PX608 <b>Result::</b> 5.4 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 40.0 <i>High</i> 64.0 <i>Unit</i> 10 <sup>9</sup> /L	New Information
Jan-05-2021 08:56:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 608 <b>Test::</b> Neutrophils_PX608 <b>Result::</b> 82.3 <b>Not Done::</b>	New Information

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			<b>Lab Normal Range:</b> <i>Low</i> 40.0  <i>High</i> 64.0  <i>Unit</i> 10 <sup>9</sup> /L	
Jan-05-2021 08:55:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 608 <b>Test::</b> Neutrophils_PX608 <b>Result::</b> 82.3 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 40.0  <i>High</i> 64.0  <i>Unit</i> %	New Information
Jan-05-2021 08:50:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 608 <b>Test::</b> Neutrophils_PX608 <b>Result::</b> 82.3 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 40.0  <i>High</i> 64.0  <i>Unit</i> 10 <sup>9</sup> /L	New Information
Jan-05-2021 08:49:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 608	New Information

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			<b>Test::</b> Neutrophils_ PX608 <b>Result::</b> 82.3 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 40.0  <i>High</i> 64.0  <i>Unit</i> %	
Dec-31-2020 13:07:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 608 <b>Test::</b> Neutrophils_ PX608 <b>Result::</b> 82.3 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 40.0  <i>High</i> 64.0	New Information
Dec-31-2020 13:06:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 608 <b>Test::</b> Neutrophils_ PX608 <b>Result::</b> 82.3 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 40.0  <i>High</i> 10.364.0	New Information
Dec-31-2020 11:31:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 608 <b>Test::</b> Neutrophils_ PX608	Transcription Error

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

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**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

			<b>Result::</b> 82.3 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 5.4 <i>High</i> 10.3	
Dec-31-2020 11:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 608 <b>Test::</b> Neutrophils_PX608 <b>Result::</b> 82.3 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>High</i> Yes	Initial Entry
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 608 <b>Test::</b> Neutrophils_PX608 <b>Result::</b> 82.3 <b>Not Done::</b> <b>Lab Normal Range:</b>	Initial Entry

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Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

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5.f Sponsor ID:

Date	Location	User	Value	Reason
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 608	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Neutrophils_PX608	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Jan-07-2021 00:32:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Jan-06-2021 10:08:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	New Information
Jan-06-2021 10:08:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 5.4	New Information
Jan-06-2021 02:21:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-06-2021	ACV0PFEINFP6000	(b) (6)	Query 3:	DM2: Please confirm

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Site No: 1252

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Subject Initials: ---

Generated By: (b) (4)

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02:12:41 (UTC-05:00) Eastern Time (US & Canada)		(b) (4)	Reissued: Opened	WBC differentials are entered as absolute or else clarify. Than you.
Jan-05-2021 08:56:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Original value is correct
Jan-05-2021 08:49:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query
Jan-05-2021 01:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued: Opened	DM: Per section 8.39.4 of CRF completion guidelines, Neutrophils, Eosinophils, Monocytes, Basophils and Lymphocytes should be entered as absolute values using 10^9/L as units. Please review and update data as per available CRF options. Else clarify.
Jan-05-2021 01:12:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: Please update Unit in Lab Normal Range field. Else, clarify.
Jan-04-2021 08:13:47 (UTC-05:00) Eastern Time (US &	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Original value is correct

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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

**Generated By:** (b) (4)

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Canada)				
Jan-04-2021 08:13:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Jan-04-2021 01:23:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-04-2021 01:18:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: Result is present, but lab normal range (Unit) is missing. Please correct or confirm
Jan-04-2021 00:23:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Opened	DMW6678826;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.

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Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family  
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Subject Initials: ---

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5.f Result:

Date	Location	User	Value	Reason
Dec-31-2020 13:08:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Low and High range submitted
Dec-31-2020 13:06:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-31-2020 11:44:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Low and High range submitted
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 82.3	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Jan-06-2021 10:09:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 1.9  <i>High</i> 7.6  <i>Unit</i> 10^9/L	New Information
Jan-05-2021 08:56:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 40.0  <i>High</i>	New Information

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Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

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			64.0 <i>Unit</i> 10^9/L	
Jan-05-2021 08:55:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 40.0  <i>High</i> 64.0  <i>Unit</i> %	New Information
Jan-05-2021 08:50:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 40.0  <i>High</i> 64.0  <i>Unit</i> 10^9/L	New Information
Jan-05-2021 08:49:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 40.0  <i>High</i> 64.0  <i>Unit</i> %	New Information
Dec-31-2020 13:07:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 40.0  <i>High</i> 64.0	New Information
Dec-31-2020 13:06:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 40.0  <i>High</i> 10.364.0	New Information

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Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Dec-31-2020 11:31:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 5.4  <i>High</i> 10.3	Transcription Error
Dec-31-2020 11:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>High</i> Yes	Initial Entry

5.g

Date	Location	User	Value	Reason
Jan-05-2021 08:58:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 609 <b>Test::</b> Eosinophils_ PX609 <b>Result::</b> 0.3 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0.00  <i>High</i> 0.50  <i>Unit</i> 10^9/L	New Information
Dec-31-2020 13:09:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 609 <b>Test::</b> Eosinophils_ PX609 <b>Result::</b> 0.3 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0.0  <i>High</i> 5.0	New Information
Dec-31-2020 11:30:33 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (6)	<b>Data Entry:</b>	Transcription Error

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

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**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

Time (US & Canada)		(b) (4)	<b>Sponsor-Defined Identifier:</b> 609 <b>Test::</b> Eosinophils_PX609 <b>Result::</b> 0.3 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0 <i>High</i> 10.3	
Dec-31-2020 11:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 609 <b>Test::</b> Eosinophils_PX609 <b>Result::</b> 0.3 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> Yes	Initial Entry
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 609 <b>Test::</b> Eosinophils_PX609 <b>Result::</b> 0.3 <b>Not Done::</b> <b>Lab Normal Range:</b>	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:28

Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.g Sponsor ID:

Date	Location	User	Value	Reason
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 609	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Eosinophils_PX609	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Jan-06-2021 01:47:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Jan-06-2021 01:47:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-05-2021 08:59:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Original value is correct
Jan-05-2021 08:57:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Jan-05-2021	ACV0PFEINFP6000	(b) (6)	Query 3:	DM: Per section

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:28

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

**Generated By:** (b) (4)

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01:14:32 (UTC-05:00) Eastern Time (US & Canada)		(b) (4)	Reissued: Opened	8.39.4 of CRF completion guidelines, Neutrophils, Eosinophils, Monocytes, Basophils and Lymphocytes should be entered as absolute values using 10 <sup>9</sup> /L as units. Please review and update data as per available CRF options. Else clarify.
Jan-04-2021 23:58:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: Please update Unit in Lab Normal Range field. Else, clarify.
Jan-04-2021 08:14:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Original value is correct
Jan-04-2021 08:14:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Jan-04-2021 01:24:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-04-2021 01:18:58 (UTC-05:00) Eastern Time (US &	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: Result is present, but lab normal range (Unit) is missing. Please correct or confirm

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Canada)				
Jan-04-2021 00:23:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Opened	DMW6678825;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Dec-31-2020 13:09:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Low and High range submitted
Dec-31-2020 13:09:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-31-2020 11:44:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Low and High range submitted
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0.3	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

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**Generated By:** (b) (4)

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Jan-05-2021 08:58:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0.00  <i>High</i> 0.50  <i>Unit</i> 10^9/L	New Information
Dec-31-2020 13:09:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0.0  <i>High</i> 5.0	New Information
Dec-31-2020 11:30:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0  <i>High</i> 10.3	Transcription Error
Dec-31-2020 11:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> Yes	Initial Entry

**5.h**

Date	Location	User	Value	Reason
Jan-06-2021 10:10:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 612 <b>Test::</b> Monocytes_P X612 <b>Result::</b> 0.5 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0.2  <i>High</i> 1.5  <i>Unit</i> 10^9/L	New Information

Header Text: c4591001

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<p>Jan-06-2021 10:10:19 (UTC-05:00) Eastern Time (US &amp; Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p><b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 612 <b>Test::</b> Monocytes_P X612 <b>Result::</b> 0.5 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 4.0 <i>High</i> 10.0 <i>Unit</i> 10^9/L</p>	<p>New Information</p>
<p>Jan-05-2021 09:01:20 (UTC-05:00) Eastern Time (US &amp; Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p><b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 612 <b>Test::</b> Monocytes_P X612 <b>Result::</b> 7.9 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 4.0 <i>High</i> 10.0 <i>Unit</i> 10^9/L</p>	<p>New Information</p>
<p>Dec-31-2020 13:10:29 (UTC-05:00) Eastern Time (US &amp; Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p><b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 612 <b>Test::</b> Monocytes_P X612 <b>Result::</b> 7.9 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 4.0 <i>High</i> 14.0</p>	<p>New Information</p>

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Header Text: c4591001

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Subject Initials: ---

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Dec-31-2020 11:29:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 612 <b>Test::</b> Monocytes_P X612 <b>Result::</b> 7.9 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0.5 <i>High</i> 10.3	Transcription Error
Dec-31-2020 11:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 612 <b>Test::</b> Monocytes_P X612 <b>Result::</b> 7.9 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>High</i> Yes	Initial Entry
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 612 <b>Test::</b> Monocytes_P X612 <b>Result::</b> 7.9 <b>Not Done::</b> <b>Lab Normal Range:</b>	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**5.h Sponsor ID:**

Date	Location	User	Value	Reason
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 612	Initial Entry

**5.h Test:**

Date	Location	User	Value	Reason
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Monocytes_PX612	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

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5.h Result:

Date	Location	User	Value	Reason
Jan-06-2021 10:10:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0.5	New Information
Jan-06-2021 01:46:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Jan-06-2021 01:46:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-05-2021 09:01:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Original value is correct
Jan-05-2021 09:01:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Answer Auto Query
Jan-05-2021 01:14:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued: Opened	DM: Per section 8.39.4 of CRF completion guidelines, Neutrophils, Eosinophils, Monocytes, Basophils and Lymphocytes

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Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Site No: 1252

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				should be entered as absolute values using 10^9/L as units. Please review and update data as per available CRF options. Else clarify.
Jan-05-2021 00:37:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	DM : Please confirm that the WBC differentials are entered as absolute values instead of percentages, or update as appropriate
Jan-04-2021 08:14:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Original value is correct
Jan-04-2021 08:14:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Original value is correct
Jan-04-2021 00:23:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Opened	DMW6678827;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Jan-03-2021 23:49:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	DM : Unit is missing in Lab Normal Ranges. Please review and update. Else, clarify.
Jan-03-2021 23:47:07 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

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Eastern Time (US & Canada)				
Dec-31-2020 13:10:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Low and High range submitted
Dec-31-2020 13:10:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-31-2020 11:45:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Low and High range submitted
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 7.9	Initial Entry

**5.h LNMT**

Date	Location	User	Value	Reason
Jan-06-2021 10:10:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Low 0.2 High	New Information



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

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**Subject Initials:** ---

**Generated By:** (b) (4)

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			1.5 <i>Unit</i> 10^9/L	
Jan-05-2021 09:01:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 4.0  <i>High</i> 10.0  <i>Unit</i> 10^9/L	New Information
Dec-31-2020 13:10:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 4.0  <i>High</i> 14.0	New Information
Dec-31-2020 11:29:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0.5  <i>High</i> 10.3	Transcription Error
Dec-31-2020 11:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>High</i> Yes	Initial Entry

**5.i**

Date	Location	User	Value	Reason
Jan-06-2021 10:22:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Id 610</b> <b>entifier:</b> <b>Test::</b> Basophils_P X610 <b>Result::</b> 0.2 <b>Not Done::</b>	New Information

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:28**Form Status:** Data Complete**Site No:** 1252**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine**Subject No:** 12521010**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51

			<b>Lab Normal Range</b> <i>Low</i> : 0.0  <i>High</i> 0.2  <i>Unit</i> 10 <sup>9</sup> /L	
Jan-05-2021 09:03:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 610 <b>Test::</b> Basophils_P X610 <b>Result::</b> 0.2 <b>Not Done::</b> <b>Lab Normal Range</b> <i>Low</i> : 0.0  <i>High</i> 1.0  <i>Unit</i> 10 <sup>9</sup> /L	New Information
Dec-31-2020 13:11:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 610 <b>Test::</b> Basophils_P X610 <b>Result::</b> 0.2 <b>Not Done::</b> <b>Lab Normal Range</b> <i>Low</i> : 0.0  <i>High</i> 2.0	New Information
Dec-31-2020 11:39:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 610 <b>Test::</b> Basophils_P X610 <b>Result::</b> 0.2	Transcription Error

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020

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Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

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			<b>Not Done::</b> <b>Lab Normal Range</b> <i>Low</i> : 0  <i>High</i> 10.3	
Dec-31-2020 11:29:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Id</b> 610 <b>entifier:</b> <b>Test::</b> Basophils_P X610 <b>Result::</b> 0.2 <b>Not Done::</b> <b>Lab Normal Range</b> <i>Low</i> : 0  <i>High</i> 10.8	Transcription Error
Dec-31-2020 11:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Id</b> 610 <b>entifier:</b> <b>Test::</b> Basophils_P X610 <b>Result::</b> 0.2 <b>Not Done::</b> <b>Lab Normal Range</b> <i>Low</i> : Yes	Initial Entry
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Id</b> 610 <b>entifier:</b> <b>Test::</b> Basophils_P X610 <b>Result::</b> 0.2 <b>Not Done::</b> <b>Lab Normal Range</b> :	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:28

Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.i Sponsor ID:

Date	Location	User	Value	Reason
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 610	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Basophils_PX610	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Jan-06-2021 01:46:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Jan-05-2021 09:03:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Original value is correct
Jan-05-2021 01:15:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-05-2021 01:15:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued: Opened	DM: Per section 8.39.4 of CRF completion guidelines, Neutrophils, Eosinophils, Monocytes, Basophils and Lymphocytes

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:28

Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

				should be entered as absolute values using 10^9/L as units. Please review and update data as per available CRF options. Else clarify.
Jan-04-2021 08:15:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Original value is correct
Jan-04-2021 08:14:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Original value is correct
Jan-04-2021 01:25:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	DM: Unit is still missing. Please consider to update. Else; clarify.
Jan-04-2021 01:24:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-04-2021 00:23:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Opened	DMW6678824;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Dec-31-2020 13:11:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Low and High range submitted

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF  
Dec/25/2020 Audit Trail History

Form Version: 10-Dec-2020 02:28

Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Canada)				
Dec-31-2020 13:11:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-31-2020 11:45:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Low and High range submitted
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Ent ry:</b> 0.2	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Jan-06-2021 10:22:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0.0  <i>High</i> 0.2  <i>Unit</i> 10^9/L	New Information
Jan-05-2021 09:03:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0.0  <i>High</i>	New Information

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:28

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

			1.0 <i>Unit</i> 10 <sup>9</sup> /L	
Dec-31-2020 13:11:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0.0 <i>High</i> 2.0	New Information
Dec-31-2020 11:39:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0 <i>High</i> 10.3	Transcription Error
Dec-31-2020 11:29:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0 <i>High</i> 10.8	Transcription Error

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF  
Dec/25/2020 Audit Trail History

Form Version: 10-Dec-2020 02:28

Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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5.i LNMT

Date	Location	User	Value	Reason
Dec-31-2020 11:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> Yes	Initial Entry

5.j

Date	Location	User	Value	Reason
Jan-06-2021 10:21:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined I 611 dentifier:</b> <b>Test::</b> Lymphocytes_ PX611 <b>Result::</b> 0.6 <b>Not Done::</b> <b>Lab Normal Rang Low e:</b> 1.1  <i>High</i> 4.8  <i>Unit</i> 10^9/L	New Information
Jan-06-2021 10:21:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined I 611 dentifier:</b> <b>Test::</b> Lymphocytes_ PX611 <b>Result::</b> 0.6 <b>Not Done::</b> <b>Lab Normal Rang Low e:</b> 22.0  <i>High</i> 44.0  <i>Unit</i> 10^9/L	New Information

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Jan-05-2021 09:03:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined I 611 dentifier:</b> <b>Test::</b> Lymphocytes_ PX611 <b>Result::</b> 8.8 <b>Not Done::</b> <b>Lab Normal Rang Low e:</b> 22.0  <i>High</i> 44.0  <i>Unit</i> 10^9/L	New Information
Dec-31-2020 13:13:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined I 611 dentifier:</b> <b>Test::</b> Lymphocytes_ PX611 <b>Result::</b> 8.8 <b>Not Done::</b> <b>Lab Normal Rang Low e:</b> 22.0  <i>High</i> 44.0	New Information
Dec-31-2020 11:38:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined I 611 dentifier:</b> <b>Test::</b> Lymphocytes_ PX611 <b>Result::</b> 8.8 <b>Not Done::</b> <b>Lab Normal Rang Low e:</b> 0.6  <i>High</i> 10.3	Transcription Error
Dec-31-2020 11:28:44 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined I 611</b>	Transcription Error

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:28

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

Time (US & Canada)		(b) (4)	<b>dentifier:</b> <b>Test::</b> Lymphocytes_ PX611 <b>Result::</b> 8.8 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 0.6  <i>High</i> 10.8	
Dec-31-2020 11:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 611 <b>dentifier:</b> <b>Test::</b> Lymphocytes_ PX611 <b>Result::</b> 8.8 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> Yes	Initial Entry
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 611 <b>dentifier:</b> <b>Test::</b> Lymphocytes_ PX611 <b>Result::</b> 8.8 <b>Not Done::</b> <b>Lab Normal Range:</b> e:	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

5.j Sponsor ID:

Date	Location	User	Value	Reason
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 611	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Lymphocytes_PX611	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Jan-06-2021 10:21:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0.6	New Information
Jan-06-2021 01:44:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Jan-05-2021 09:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Original value is correct
Jan-05-2021 01:16:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued: Opened	DM: Per section 8.39.4 of CRF completion guidelines, Neutrophils, Eosinophils, Monocytes, Basophils and Lymphocytes

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:28**Form Status:** Data Complete**Site No:** 1252**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine**Subject No:** 12521010**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51

				should be entered as absolute values using 10 <sup>9</sup> /L as units. Please review and update data as per available CRF options. Else clarify.
Jan-05-2021 01:15:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-04-2021 08:15:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Original value is correct
Jan-04-2021 08:15:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Jan-04-2021 01:25:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: Unit is still missing. Please consider to update. Else; clarify.
Jan-04-2021 01:25:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-04-2021 00:23:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Opened	DMW6678763;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

				correct as appropriate.
Dec-31-2020 13:13:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Low and High range submitted
Dec-31-2020 13:13:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-31-2020 11:45:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Low and High range submitted
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Dec-31-2020 11:02:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 8.8	Initial Entry

**5.j LNMT**

Date	Location	User	Value	Reason
Jan-06-2021 10:21:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 1.1  <i>High</i> 4.8  <i>Unit</i>	New Information

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:28

Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

			10^9/L	
Jan-05-2021 09:03:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 22.0  <i>High</i> 44.0  <i>Unit</i> 10^9/L	New Information
Dec-31-2020 13:13:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 22.0  <i>High</i> 44.0	New Information
Dec-31-2020 11:38:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0.6  <i>High</i> 10.3	Transcription Error
Dec-31-2020 11:28:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0.6  <i>High</i> 10.8	Transcription Error
Dec-31-2020 11:14:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> Yes	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - Audit Trail  
Dec/25/2020

**Form Version:** 21-Aug-2020 02:50

**Form Status:**

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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Date	Location	User	Value	Reason
Jan-05-2021 16:03:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: VITAL SIGNS - COVID - eCRF Audit Trail History  
Dec/25/2020

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**I. Date:**

Date	Location	User	Value	Reason
Jan-05-2021 16:03:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/25/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Jan-05-2021 16:03:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Systolic::</b> 12 4 <b>Diastolic::</b> 68 <b>Respiratory Rate in respiratio</b> <b>ns/minute:</b> 20 <b>Heart Rate in beats/minute:</b> 79	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Jan-05-2021 16:03:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Systolic:**

Date	Location	User	Value	Reason
Jan-05-2021 16:03:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 124	Initial Entry

**2.a Diastolic:**

Date	Location	User	Value	Reason
Jan-05-2021 16:03:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 68	Initial Entry

**2.a Respiratory Rate in respirations/minute:**

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History  
Dec/25/2020

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Data Complete

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Jan-05-2021 16:03:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 20	Initial Entry

**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Jan-05-2021 16:03:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 79	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - Audit Trail  
Dec/25/2020

**Form Version:** 10-Dec-2020 02:25

**Form Status:**

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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Date	Location	User	Value	Reason
Jan-21-2021 08:45:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Jan-21-2021 08:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Undeleted	Transcription Error
Jan-05-2021 16:03:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Dec-30-2020 17:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: VITAL SIGNS - COVID - eCRF Audit Trail History  
Dec/25/2020

Form Version: 10-Dec-2020 02:25

Form Status: Incomplete, Data Complete, Deleted

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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I. Date:

Date	Location	User	Value	Reason
Jan-21-2021 08:44:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-30-2020 17:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/25/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-21-2021 08:43:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Systolic::</b> <b>Diastolic::</b> <b>Respiratory Rate in respiratio ns/minute:</b> <b>Heart Rate in beats/minute:</b>	Transcription Error
Jan-21-2021 08:43:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Systolic::</b> <b>Diastolic::</b> <b>Respiratory Rate in respirati ons/minute:</b> <b>Heart Rate in beats/minute:</b> 7 9	Transcription Error
Jan-21-2021 08:42:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Systolic::</b> <b>Diastolic::</b> <b>Respiratory Rate in respirati ons/minute:</b> 2 0 <b>Heart Rate in beats/minute:</b> 7 9	Transcription Error

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Jan-21-2021 08:42:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Systolic::</b> <b>Diastolic::</b> 6 8 <b>Respiratory Rate in respirati ons/minute:</b> 2 0 <b>Heart Rate in beats/minute:</b> 7 9	Transcription Error
Dec-30-2020 17:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Systolic::</b> 12 4 <b>Diastolic::</b> 68 <b>Respiratory Rate in respirati ons/minute:</b> 20 <b>Heart Rate in beats/minute:</b> 79	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Dec-30-2020 17:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Systolic:**

Date	Location	User	Value	Reason
Jan-21-2021 08:42:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-30-2020 17:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 124	Initial Entry

**2.a Diastolic:**

Date	Location	User	Value	Reason
Jan-21-2021 08:42:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-30-2020 17:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 68	Initial Entry

**2.a Respiratory Rate in respirations/minute:**

Date	Location	User	Value	Reason
Jan-21-2021 08:43:06 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (6)	<b>Data Entry:</b>	Transcription Error

Time (US & Canada)		(b) (4)		
Dec-30-2020 17:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 20	Initial Entry

**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Jan-21-2021 08:43:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-30-2020 17:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 79	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail  
Dec/25/2020

**Form Version:** 21-Aug-2020 02:51

**Form Status:**

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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Date	Location	User	Value	Reason
Jan-21-2021 08:38:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Undeleted	Transcription Error
Jan-12-2021 09:27:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Changed Information
Jan-05-2021 16:13:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History  
Dec/25/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**I. Date:**

Date	Location	User	Value	Reason
Jan-05-2021 16:13:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/25/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Jan-05-2021 16:13:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Oxygen Saturation:</b> 98.0	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Jan-05-2021 16:13:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a SPO2 Pulse Oximetry %**

Date	Location	User	Value	Reason
Jan-05-2021 16:13:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.0	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail  
Dec/25/2020

**Form Version:** 10-Dec-2020 02:31

**Form Status:**

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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Date	Location	User	Value	Reason
Jan-21-2021 08:45:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Jan-21-2021 08:41:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Undeleted	Transcription Error
Jan-05-2021 16:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Dec-30-2020 17:18:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History  
Dec/25/2020

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Deleted

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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**I. Date:**

Date	Location	User	Value	Reason
Dec-30-2020 17:18:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/25/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Dec-30-2020 17:18:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Oxygen Saturation:</b> 98.0	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Dec-30-2020 17:18:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a SPO2 Pulse Oximetry %**

Date	Location	User	Value	Reason
Dec-30-2020 17:18:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.0	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS - Audit Trail  
Dec/25/2020

**Form Version:** 06-Jul-2020 21:52

**Form Status:**

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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Date	Location	User	Value	Reason
Jan-21-2021 08:40:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Undeleted	Transcription Error
Jan-12-2021 09:31:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Changed Information
Jan-12-2021 09:30:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Undeleted	Changed Information
Jan-12-2021 09:30:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Changed Information

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: OXYGENATION PARAMETERS - eCRF Audit Trail History  
Dec/25/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Date Time of Assessment:**

Date	Location	User	Value	Reason
Dec-31-2020 12:37:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Arterial Blood Gases PaO2 (mmHg):**

Date	Location	User	Value	Reason
Dec-31-2020 12:37:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. FiO2 (Fraction of Inhaled Oxygen):**

Date	Location	User	Value	Reason
Dec-31-2020 12:37:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Audit Trail Dec/25/2020

**Form Version:** 06-Jul-2020 21:55

**Form Status:**

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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Date	Location	User	Value	Reason
Jan-21-2021 08:40:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Undeleted	Transcription Error
Jan-12-2021 09:31:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Changed Information

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Jan-08-2021 08:39:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Jan-08-2021 08:39:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Jan-08-2021 08:39:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Medication:**

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Jan-08-2021 08:39:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Jan-05-2021 08:23:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Dec-31-2020 12:22:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
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090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History  
**Form Version:** 06-Jul-2020 21:55 **Form Status:** Data Complete, Frozen  
**Site No:** 1252 **Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine  
**Subject No:** 12521010 **Subject Initials:** ---  
**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

Jan-11-2021 00:50:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-08-2021 08:39:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Jan-08-2021 08:39:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	NOT APPLICABLE
Jan-08-2021 01:28:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM2 : Please review and add the form level comment as Not Applicable on this form. Thank you.
Jan-07-2021 08:40:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	NOT APPLICABLE
Jan-07-2021 06:26:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM1: Form level 'Not Applicable' comment not applied. Please remove existing item level comments and add new form level 'Not Applicable' comment. Refer to section 4.11.3/4.10 of completion guidelines. Contact CRA if needed.
Jan-06-2021 10:42:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Jan-06-2021 03:51:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM2: Data is not updated per query. Kindly refer CCG section 4.11.3 to clear item level comment on this form and refer to CCG section 4.10 to add new Form level 'Not

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Dec/25/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:55**Form Status:** Data Complete, Frozen**Site No:** 1252**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine**Subject No:** 12521010**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51

				Applicable' on this form. Else clarify.
Jan-05-2021 08:24:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Jan-05-2021 08:24:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Not Done
Jan-05-2021 00:46:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM1: Kindly consider updating form level comment Not Applicable. Thank you.
Jan-04-2021 08:16:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Not applicable
Jan-04-2021 00:41:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Kindly consider to update this form if require else mark as Not applicable by selecting form level comment. Thank you.

**6. Ongoing?**

Date	Location	User	Value	Reason
Jan-08-2021 08:39:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Jan-05-2021 08:24:49 (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 on **Form:** IMAGING - Audit Trail  
Dec/25/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:**

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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Date	Location	User	Value	Reason
Jan-21-2021 08:40:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Undeleted	Transcription Error
Jan-12-2021 09:31:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Changed Information
Dec-31-2020 12:33:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: IMAGING - eCRF Audit Trail History  
Dec/25/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Dec-31-2020 12:33:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/25/2020	Initial Entry

**2. Location of Assessment:**

Date	Location	User	Value	Reason
Dec-31-2020 12:33:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHEST	Initial Entry

**3. Type of Imaging Exam:**

Date	Location	User	Value	Reason
Dec-31-2020 12:33:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> X-RAY	Initial Entry

**4. Assessment:**

Date	Location	User	Value	Reason
Dec-31-2020 12:33:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ABNORMAL <i>If abnormal, specify findings:</i>  An enlarged heart	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_CONVA 1 - Unscheduled Visit on Dec/26/2020**Form Version:** 22-Apr-2020 21:04**Site No:** 1252**Subject No:** 12521010**Generated By:** (b) (4)**Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)*I. Date of Visit*

Date	Location	User	Value	Reason
Feb-16-2021 12:34:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-16-2021 08:08:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Need the page unfrozen to correct
Feb-11-2021 23:15:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM : Visit is marked as Erroneous. However, data is still present on SAMP TRK CRF. Please review and add form level comment as Not Applicable on SAMP TRK form. Else, clarify.
Feb-11-2021 08:32:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Marked not done
Feb-11-2021 06:29:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Feb-10-2021 15:55:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-10-2021 15:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	No Convalescent visit for the subject passed away on 26Dec2020

**Header Text:** c4591001**Visit:** POT\_COVID\_CONVA 1 - Unscheduled Visit on Dec/26/2020**Form Version:** 22-Apr-2020 21:04**Site No:** 1252**Subject No:** 12521010**Generated By:** (b) (4)**Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51

Feb-10-2021 15:10:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Feb-09-2021 10:40:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	CLIQUEY: Thank you for update. Please indicate CONV visit as Erroneous then on CRF.
Feb-09-2021 09:49:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Visit was not done since patient died on 26Dec2020
Feb-09-2021 08:18:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLIQUEY: Please clarify as CONVALESCENT visit was only one day after the COVID_A ILL visit? Per protocol CONV visit should occur 28-35 days after COVID ILL visit.
Feb-08-2021 13:36:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/26/2020	Initial Entry

**2. Erroneous Visit**

Date	Location	User	Value	Reason
Feb-10-2021 15:10:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ERRONEOUS VISIT	Initial Entry

**3. COVID-19 Illness Visit:**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Dec/26/2020

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1252

**Subject No:** 12521010

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail  
History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

Feb-11-2021 11:01:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-11-2021 08:32:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Feb-10-2021 15:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-10-2021 15:10:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Feb-10-2021 15:10:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COVID_A1	Initial Entry
Feb-10-2021 03:36:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Please complete this item. Thank you.
Feb-09-2021 09:47:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-08-2021 13:59:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COVID_A1	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Dec/26/2020

Form Version: 22-Apr-2020 21:03

Site No: 1252

Subject No: 12521010

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Data Origin**

Date	Location	User	Value	Reason
Feb-16-2021 10:06:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Done	Initial Entry
Feb-16-2021 10:06:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Feb-08-2021 13:59:30 (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
Feb-16-2021 10:06:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Done	Initial Entry
Feb-16-2021 10:06:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Feb-08-2021 13:59:30 (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
Feb-16-2021 10:06:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Feb-16-2021 10:06:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-08-2021 13:59:30 (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\_CONVA 1 - Unscheduled  
Visit on Dec/26/2020

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1252

**Subject No:** 12521010

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Feb-16-2021 10:06:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Done	Initial Entry
Feb-16-2021 10:06:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-08-2021 13:59:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Patient died 26Dec2020	Initial Entry

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1252

**Subject No:** 12521010

**Generated By:** (b) (4)

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Oct-05-2020 15:06:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/5/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-05-2020 15:06:56 (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-05-2020 15:06:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

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**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1252

**Subject No:** 12521010

**Generated By:** (b) (4)

**Form:** DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Dec-29-2020 11:44:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/26/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Dec-29-2020 11:44:06 (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
Dec-29-2020 11:44:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DEATH	Initial Entry

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**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1252

**Subject No:** 12521010

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Date	Location	User	Value	Reason
Dec-21-2020 11:23:21 (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:** 1252

**Subject No:** 12521010

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Date	Location	User	Value	Reason
Dec-29-2020 11:39:40 (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:** 1252

**Subject No:** 12521010

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Date	Location	User	Value	Reason
Jan-26-2021 15:14:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1252

Subject No: 12521010

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Category:**

Date	Location	User	Value	Reason
Dec-21-2020 11:23:21 (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
Dec-21-2020 11:23:21 (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
Dec-21-2020 11:23:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Scalp Laceration	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Dec-21-2020 11:23:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/8/2020 19:05	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Dec-21-2020 11:23:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Dec/8/2020 20:30	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Dec-21-2020 11:23:21 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

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Site No: 1252

Subject No: 12521010

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject Initials: ---

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(US & Canada)

(b) (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).

Date	Location	User	Value	Reason
Dec-21-2020 11:23:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Dec-21-2020 11:23:21 (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
Jan-04-2021 10:52:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-29-2020 08:22:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Felled backwards in chair and bumped his head.
Dec-28-2020 18:19:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	GPD CLIN: Please clarify if accident was considered a Motor Vehicle Accident (MVA). If confirmed a MVA, please reference CRF CG 80.50.2 and update the CRF as appropriate. Else clarify.

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Form Version: 22-Apr-2020 21:02

Site No: 1252

Subject No: 12521010

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject Initials: ---

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Dec-28-2020 12:05:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Accident
Dec-28-2020 12:05:59 (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>  Accident	Accident
Dec-23-2020 14:04:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Please clarify if the event of scalp laceration was due to an accident or injury and update the CRF as appropriate.
Dec-21-2020 11:23:21 (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>  Scalp Laceration	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-21-2020 11:23:21 (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
Dec-21-2020 11:23:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Dec-21-2020 11:23:21 (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
Dec-21-2020 11:23:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Dec-21-2020 11:23:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

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Site No: 1252

Subject No: 12521010

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject Initials: ---

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**1. Category:**

Date	Location	User	Value	Reason
Dec-29-2020 11:39:40 (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
Dec-29-2020 11:39:40 (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
Jan-27-2021 13:21:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Closed	Response satisfies query
Jan-26-2021 15:14:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Changed data per query
Jan-25-2021 16:14:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 3: Opened	As per update to safety narrative, subject was in acute renal failure. However this information is missing on AElog of CRF. Please review and update accordingly.
Jan-02-2021 14:57:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Jan-02-2021 14:57:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Closed	Response satisfies query

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)



Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1252

Subject No: 12521010

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

Dec-30-2020 17:22:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Dec-30-2020 17:03:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	No nasal swab was collected for central lab.
Dec-30-2020 09:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Opened	Clin: Please confirm if a nasal swab was collected for the central laboratory. If the local lab collected more than one nasal swab that could be eventually used by the Pfizer central lab.
Dec-30-2020 09:18:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Medical monitor: Despite telehealth visit was not done, please complete the potential COVID-19 Illness Visit CRF forms with all information available. Should be captured also on the SOD CRF form
Dec-29-2020 11:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Pneumonia due to COVID-19	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-29-2020 11:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/25/2020 22:03	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-29-2020 11:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1252

Subject No: 12521010

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject Initials: ---

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			Dec/26/2020 09:55	
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6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-29-2020 11:39:40 (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
Jan-02-2021 01:44:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-29-2020 11:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Pneumonia due to COVID-19 : Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-29-2020 11:39:40 (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?	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1252

Subject No: 12521010

Generated By: (b) (4)

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			YES  Did this serious event result in persistent or significant disability/incapacity?  NO  Is this serious event life threatening?  YES  Other medically important serious event  NO	
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8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Dec-29-2020 11:39:40 (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
Dec-29-2020 11:39:40 (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  If Other, specify:  Pneumonia	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-25-2021 12:27:57 (UTC-05:00)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 6: Clo sed	Response satisfies query

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1252

**Subject No:** 12521010

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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Eastern Time (US & Canada)				
Feb-25-2021 10:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Answered	Transcription Error
Feb-25-2021 10:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : NOT APPLICABLE	Transcription Error
Feb-25-2021 06:03:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Opened	CLINQUERY: DRUG WITHDRAWN is reported. However, subject received both doses of vaccine prior to this event. Please review entry. An update will need a matching SAE report update for the Safety database
Feb-23-2021 06:51:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 6: Candidate	CLINQUERY: DRUG WITHDRAWN is reported. However, subject received both doses of vaccine prior to this event. Please review entry. An update will need a matching SAE report update for the Safety database
Feb-18-2021 03:19:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Response satisfies query
Feb-17-2021 09:40:00 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Answered	Transcription Error

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(US & Canada)				
Feb-17-2021 09:40:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : DRU G WI THD RAW N	Transcription Error
Feb-16-2021 21:33:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Op ened	SAE RECON:AER#2020518879 .action taken was updated to NOT APPLICABLE in AE CRF while PERMANENTLY WITHDRAWN in Safety database.Please confirm correct action taken. If safety update is required, submit a follow up form.
Feb-15-2021 12:18:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : NOT APPL ICAB LE	Transcription Error
Jan-28-2021 09:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Clo sed	Response satisfies query
Jan-26-2021 14:56:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : DRU G WI THD RAW N	New Information
Jan-26-2021 12:31:22	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Ans	Transcription error

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(UTC-05:00) Eastern Time (US & Canada)			wered	
Jan-26-2021 09:59:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Rei ssued: Opene d	SAE RECON 2: Please confirm Action taken since its "NOT APPLICABLE" in AE CRF and "PERMANENTLY WITHDRAWN" in safety database. Please review and update the appropriate database with the correct Action Taken. Thanks
Jan-25-2021 10:57:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Ans wered	Permanently withdrawn.
Jan-22-2021 13:12:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Rei ssued: Opene d	SAE RECON 1: ,action taken was reported as NOT APPLICABLE in AE CRF while PERMANENTLY WITHDRAWN in Safety database. Please confirm if a follow up SAE form has been submitted to update safety database otherwise review CRF.
Jan-21-2021 09:20:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Ans wered	Transcription error
Jan-20-2021 22:17:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Op ened	SAE RECON:AER#2020518879 ,action taken was reported as NOT APPLICABLE in AE CRF while PERMANENTLY WITHDRAWN in Safety database.Please submit a follow up form to update

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				action taken in Safety database.
Jan-19-2021 10:40:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 3: Clo sed	Response satisfies query
Jan-19-2021 08:16:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Ans wered	Transcription Error
Jan-19-2021 08:16:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : NOT APPL ICAB LE	Transcription Error
Jan-19-2021 06:29:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 3: Op ened	CLINQUERY: Drug Withdrawn is reported. However, subject had received both Vax 1 and Vax 2. Please review entry; else, clarify
Jan-18-2021 20:48:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Clo sed	Response satisfies query
Jan-18-2021 08:21:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Ans wered	Transcription Error
Jan-18-2021 08:21:35 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : DRU	Transcription Error

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**Site No:** 1252

**Subject No:** 12521010

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

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(US & Canada)			G W I T H D R A W N	
Jan-17-2021 05:13:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Op ened	SAE RECON:AER#2020518879 ,action taken was reported as NOT APPLICABLE in AE CRF while PERMANENTLY WOTHDRAWN in Safety database.Please confirm. If safety update is required, please submit a follow up form
Jan-15-2021 16:00:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Clo sed	Auto closed by Validation Check: VC_AE001_32
Jan-15-2021 09:06:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Transcription Error
Jan-15-2021 09:06:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : NOT APPL ICAB LE	Transcription Error
Jan-14-2021 23:47:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW6842219;The Latest Action to Study Treatment is DRUG WITHDRAWN, but the Disposition- Treatment Form Status is not DEATH OR ADVERSE EVENT. Please review and update as appropriate.

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Form Status: Data Complete, Frozen

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Subject Initials: ---

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**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Dec-29-2020 11:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DRUG WITHDRAWN	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Dec-29-2020 11:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Dec-29-2020 11:39:40 (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
Dec-29-2020 11:41:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-29-2020 11:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	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.
Dec-29-2020 11:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FATAL	Initial Entry

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**Header Text:** c4591001

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**Site No:** 1252

**Subject No:** 12521010

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

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**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Dec-29-2020 11:39:40 (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
Jan-02-2021 01:44:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2020518879	Initial Entry

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Subject No: 12521010

Generated By: (b) (4)

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**1. Category:**

Date	Location	User	Value	Reason
Jan-26-2021 15:14:04 (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
Jan-26-2021 15:14:04 (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
Jan-28-2021 11:07:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-28-2021 10:59:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Per medical records the subject did not have a history of renal disease or dysfunction.
Jan-28-2021 10:30:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: pls confirm subject has no past hx of renal disease/dysfunction. Thanks
Jan-26-2021 15:14:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Acute Renal failure	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Jan-26-2021 15:14:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/25/2020 22:03	Initial Entry

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Subject No: 12521010

Generated By: (b) (4)

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Form Status: Data Complete, Frozen

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-26-2021 15:14:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Dec/26/2020 09:55	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-26-2021 15:14:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Jan-26-2021 15:14:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Jan-26-2021 15:14:04 (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
Jan-26-2021 15:14:04 (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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			OTHER	
			<i>If Other, specify:</i>	
			Kidney damage	

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-27-2021 16:32:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-27-2021 07:23:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-27-2021 07:23:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Transcription Error
Jan-27-2021 04:54:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	As per End of Treatment form, Treatment was completed on 5 Oct 2020 which is prior to the AE Start and Stop date, Please confirm if Action Taken with Study Treatment should be updated as "Not Applicable", Thank you. (b) (4)
Jan-26-2021 15:14:04	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DRUG WIT	Initial Entry

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(UTC-05:00) Eastern Time (US & Canada)			HDRAWN	
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-26-2021 15:14:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-26-2021 15:14:04 (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
Jan-26-2021 15:17:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-26-2021 15:17:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Transcription Error
Jan-26-2021 15:14:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Acute Renal failure: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Jan-26-2021 15:14:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNKNOWN	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1252

**Subject No:** 12521010

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Jan-26-2021 15:14:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1252

Subject No: 12521010

Generated By: (b) (4)

Form: MEDICATION ERROR - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Category:**

Date	Location	User	Value	Reason
Dec-21-2020 11:23:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Medication Error (Type of Medication Error):**

Date	Location	User	Value	Reason
Dec-21-2020 11:23:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Start Date:**

Date	Location	User	Value	Reason
Dec-21-2020 11:23:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Is the medication error still ongoing?**

Date	Location	User	Value	Reason
Dec-21-2020 11:23:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Dec-21-2020 11:23:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Dec-21-2020 11:23:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1252

**Subject No:** 12521010

**Generated By:** (b) (4)

**Form:** MEDICATION ERROR - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**7. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Dec-21-2020 11:23:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**8. Did the Medication Error cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Dec-21-2020 11:23:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**9. Was this medication error associated with any adverse events?**

Date	Location	User	Value	Reason
Dec-21-2020 11:23:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**10. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Dec-21-2020 11:23:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS - Audit Trail

**Form Version:** 22-Apr-2020 21:03

**Form Status:**

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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Date	Location	User	Value	Reason
Dec-21-2020 11:27:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS - Audit Trail

**Form Version:** 22-Apr-2020 21:03

**Form Status:**

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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Date	Location	User	Value	Reason
Dec-21-2020 11:29:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS - Audit Trail

**Form Version:** 22-Apr-2020 21:03

**Form Status:**

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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Date	Location	User	Value	Reason
Dec-21-2020 11:34:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**I. What is the medication identifier?**

Date	Location	User	Value	Reason
Dec-21-2020 13:29:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-21-2020 11:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Dec-21-2020 11:46:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry
Dec-21-2020 11:43:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Dec-21-2020 11:37:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry
Dec-21-2020 11:31:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Dec-21-2020 11:27:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Dec-21-2020 13:29:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-21-2020 11:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Dec-21-2020 11:46:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATIONS	Initial Entry

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Header Text: c4591001

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Form Status: Data Complete, Frozen, Verified

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

Dec-21-2020 11:43:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Dec-21-2020 11:37:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> VACCINATIONS	Initial Entry
Dec-21-2020 11:31:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Dec-21-2020 11:27:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> VACCINATIONS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Dec-21-2020 13:29:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Not Applicable	Initial Entry
Dec-21-2020 11:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Dec-21-2020 11:46:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NO	Initial Entry
Dec-21-2020 11:43:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Dec-21-2020 11:37:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NO	Initial Entry
Dec-21-2020 11:31:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Dec-21-2020 11:27:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NO	Initial Entry

**4. Medication:**

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Header Text: c4591001

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Form Status: Data Complete, Frozen, Verified

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

*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-21-2020 13:29:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-21-2020 11:46:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-21-2020 11:46:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not applicable	Initial Entry
Dec-21-2020 11:43:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-21-2020 11:37:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ondansetron 4 mg 2 ml injection	Initial Entry
Dec-21-2020 11:31:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-21-2020 11:27:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Ondansetron 4 mg 2 ml	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Dec-21-2020 13:29:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-21-2020 11:51:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-21-2020 11:46:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/8/2020	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
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**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

Dec-21-2020 11:43:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-21-2020 11:37:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/8/2020	Initial Entry
Dec-21-2020 11:32:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-21-2020 11:27:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/8/2020	Initial Entry



Header Text: c4591001

Visit: Logs - Unscheduled

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Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Dec-21-2020 13:30:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-21-2020 11:43:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Dec-21-2020 11:38:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry
Dec-21-2020 11:33:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Dec-21-2020 11:29:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Dec-21-2020 13:30:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-21-2020 11:43:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Dec-21-2020 11:38:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATIONS	Initial Entry
Dec-21-2020 11:33:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Dec-21-2020 11:29:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATIONS	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY  
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Form Status: Data Complete, Frozen, Verified

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Dec-21-2020 13:30:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-21-2020 11:43:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Dec-21-2020 11:38:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry
Dec-21-2020 11:33:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Dec-21-2020 11:29:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Dec-21-2020 13:30:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-21-2020 11:43:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-21-2020 11:38:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Lidocaine-epinephrine 1%-1:100,0 00 injectable solution	Initial Entry
Dec-21-2020 11:33:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-21-2020 11:29:20 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (6)	<b>Data Entry:</b> Lidocaine-epinephrine 1%-1:100,0	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

Time (US & Canada)		(b) (4)	00 injectable solution	
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**5. Date:**

Date	Location	User	Value	Reason
Dec-21-2020 13:30:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-21-2020 11:44:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-21-2020 11:38:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/8/2020	Initial Entry
Dec-21-2020 11:33:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-21-2020 11:29:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/8/2020	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

**Subject No:** 12521010

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Dec-21-2020 13:30:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-21-2020 11:45:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Dec-21-2020 11:34:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Dec-21-2020 13:30:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-21-2020 11:45:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Dec-21-2020 11:34:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATIONS	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Dec-21-2020 13:30:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-21-2020 11:45:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Dec-21-2020 11:34:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family  
Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

**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-21-2020 13:30:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-21-2020 11:45:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-21-2020 11:34:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not applicable	Initial Entry

**5. Date:**

Date	Location	User	Value	Reason
Dec-21-2020 13:30:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Dec-21-2020 11:45:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Dec-21-2020 11:34:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/8/2020	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1252

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject No: 12521010

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Dec-21-2020 11:40:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Dec-21-2020 11:40:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Dec-21-2020 11:40:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Medication:**

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Dec-21-2020 11:40:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Dose:**

Date	Location	User	Value	Reason
Dec-21-2020 11:40:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Dose Unit:**

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1252

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject No:** 12521010

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

Date	Location	User	Value	Reason
Dec-21-2020 11:40:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**7. Dose Frequency:**

Date	Location	User	Value	Reason
Dec-21-2020 11:40:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**8. Route:**

Date	Location	User	Value	Reason
Dec-21-2020 11:40:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**9. Start Date:**

Date	Location	User	Value	Reason
Dec-21-2020 11:40:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**10. Ongoing?**

Date	Location	User	Value	Reason
Dec-21-2020 11:40:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1252

Subject No: 12521010

Generated By: (b) (4)

Form: RADIATION TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Category:**

Date	Location	User	Value	Reason
Dec-21-2020 11:41:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. What is the treatment Identifier?**

Date	Location	User	Value	Reason
Dec-21-2020 11:41:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Concomitant Non-drug Treatment Pre-specified:**

Date	Location	User	Value	Reason
Dec-21-2020 11:41:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Treatment:**

Date	Location	User	Value	Reason
Dec-21-2020 11:41:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Dec-21-2020 11:41:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Ongoing?**

Date	Location	User	Value	Reason
Dec-21-2020 11:41:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1252

**Subject No:** 12521010

**Generated By:** (b) (4)

**Form:** TRANSFUSIONS - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Transfusion Type:**

Date	Location	User	Value	Reason
Dec-21-2020 11:41:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Date of Transfusion:**

Date	Location	User	Value	Reason
Dec-21-2020 11:41:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1252

**Subject No:** 12521010

**Generated By:** (b) (4)

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Jan-05-2021 09:24:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Jan-05-2021 09:24:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1252

**Subject No:** 12521010

**Generated By:** (b) (4)

**Form:** WITHDRAWAL OF CONSENT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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*I. Withdrawal of Consent Date :*

Date	Location	User	Value	Reason
Jan-05-2021 09:24:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1252

**Subject No:** 12521010

**Generated By:** (b) (4)

**Form:** DEATH DETAILS CODED - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**I. Date of Collection / Notification of Death:**

Date	Location	User	Value	Reason
Jan-06-2021 01:26:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-05-2021 09:23:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	The subject passed on 26Dec2020. We were not notified or knew of his death until 29Dec2020. The original information given on the date of collection or notification of his death is correct.
Jan-05-2021 08:03:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM 1: Kindly review and update the Date of Collection / Notification of Death recorded as the date is after the date (26/Dec /2020) on the disposition follow up form.
Jan-04-2021 07:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candidate	Issue added in DM Meeting and Q & A sheet.
Dec-31-2020 09:03:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Original value is correct
Dec-31-2020 08:29:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: Per CRF, Date of Collection / Notification of Death is after the Date of Completion/Discontinuation /Death on the Disposition form 26/Dec/2020. If Date on this page is correct then please update details on 'DISP FUP' page. Else clarify.
Dec-31-2020 08:29:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	DM: Per CRF, Date of Collection / Notification of Death is after the Date of

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1252

**Subject No:** 12521010

**Generated By:** (b) (4)

**Form:** DEATH DETAILS CODED - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

				Completion/Discontinuation /Death on the Disposition form 26/Dec/2020. If Date on this page is correct then please update details on 'DISP FUP' page. Else clarify.
Dec-29-2020 11:46:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Family informed site of subject's death on 29Dec2020
Dec-29-2020 11:44:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of Collection / Notification of Death is greater than the Date of Completion/Discontinuation /Death on the Disposition form 26/Dec/2020. Please review and update as appropriate
Dec-29-2020 11:41:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/29/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Dec-29-2020 11:42:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Cause of Death Status:</b> PRIMARY CAUSE OF DEATH <b>Cause of Death h:</b> Pneumonia due to COVID-19	Initial Entry

**2.a Cause of Death Status:**

Date	Location	User	Value	Reason
Dec-29-2020 11:42:23 (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
Dec-29-2020 11:42:23 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (6)	<b>Data Entry:</b> Pneumonia due to COVID-19	Initial Entry

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1252

**Subject No:** 12521010

**Generated By:** (b) (4)

**Form:** DEATH DETAILS CODED - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

(US & Canada)

(b) (4)

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1252

Subject No: 12521010

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Subject Status**

Date	Location	User	Value	Reason
Dec-29-2020 11:44:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Initial Entry
Oct-05-2020 15:06:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-21-2020 06:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-21-2020 06:22:34 (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
Dec-29-2020 11:44:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Dec/26/2020	Initial Entry
Oct-05-2020 15:06:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/5/2020	Initial Entry
Aug-21-2020 06:23:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/17/2020	Initial Entry
Aug-21-2020 06:22:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/17/2020	Initial Entry

090177e196ae30e6\Final\Final On: 01-Apr-2021 04:19 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1252

**Subject No:** 12521010

**Generated By:** (b) (4)

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

**Form Status:** Data Complete, Signed, Verified

**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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*1. Casebook Signature*

Date	Location	User	Value	Reason
Oct-21-2020 17:09:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry