

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1252

Subject No: 12521011

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

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001	Form: MAIN INFORMED CONSENT
Visit: COHORT_SELECTION	Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 22-Apr-2020 21:02	Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine
Site No: 1252	Subject Initials: ---
Subject No: 12521011	Generated Time (GMT): 29-Mar-2021 18:51
Generated By: (b) (4)	

[eCRF Audit Trail History](#)

Informed Consent							
1.	<table border="0"> <tr> <td>Consent Was:</td> <td>OBTAINED</td> </tr> <tr> <td></td> <td>Date Written Consent Obtained</td> </tr> <tr> <td></td> <td>Aug/17/2020</td> </tr> </table>	Consent Was:	OBTAINED		Date Written Consent Obtained		Aug/17/2020
Consent Was:	OBTAINED						
	Date Written Consent Obtained						
	Aug/17/2020						

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1252

Subject No: 12521011

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	[12521011]
2.	Birth Date:	(b) (6) 1935
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: 12521011

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: 12521011

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
----	--	----------------

Exclusion Criteria Met

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

090177e196ae30e7\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: 12521011

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: 12521011

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:	[Anxiety]
	Start Date:	Mar/4/2019
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[Chronic obstructive lung disease]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[Insomnia]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[Depression]
	Start Date:	Apr/9/2018
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[Hypogonadism]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[Osteoarthritis in back]
	Start Date:	UNK/UNK/2009
	Ongoing:	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1252

Subject No: 12521011

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

1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[Gerd]
	Start Date:	UNK/UNK/2008
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[Benign Prostatic Hyperplasia]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[Coronary artery disease]
	Start Date:	Apr/UNK/2018
	Ongoing:	YES
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:	[Angioplasty]
	Start Date:	Apr/9/2018
	Ongoing:	NO End Date: Apr/9/2018

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1252

Subject No: 12521011

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:	[140.0]
3.	Unit:	LB
4.	Height:	[68.0]
5.	Unit:	in
6.	Body Mass Index:	[21.3]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.2]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae30e7\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: 12521011

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:	[230752]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1252

Subject No: 12521011

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	[BNWG1M]
5.b	Sample ID	[BNWG1N]
5.c	Sample ID	[BPYXM3]
5.d	Sample ID	[BPYXM4]
5.e	Sample ID	[BPYXM5]

090177e196ae30e7\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: 12521011

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	[BPYXLT]
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090177e196ae30e7\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: 12521011

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 16:50
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

090177e196ae30e7\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: 12521011

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	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1252

Subject No: 12521011

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/9/2020
2.	Erroneous Visit	

090177e196ae30e7\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: 12521011

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/9/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.8]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1252

Subject No: 12521011

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/9/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPYXZ7]
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090177e196ae30e7\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: 12521011

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/9/2020 09:40
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

090177e196ae30e7\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: 12521011

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/12/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1252

Subject No: 12521011

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/12/2020
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	[BPYY3H]
5.b	Sample ID	[BPYY3J]
5.c	Sample ID	[BPYY3K]
5.d	Sample ID	[BNWG4X]
5.e	Sample ID	[BNWG4Y]

090177e196ae30e7\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: 12521011

Generated By: (b) (4)

Form: DATE OF VISIT

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](#)

Date of Visit

1.	Date of Visit	Mar/10/2021
2.	Erroneous Visit	

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/10/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPYY6P]
5.b	Sample ID	[BNWG88]
5.c	Sample ID	[BNWG89]

090177e196ae30e7\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: 12521011

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	

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1252

Subject No: 12521011

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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Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1252

Subject No: 12521011

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: 12521011

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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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021

Form: DATE OF VISIT - ILLNESS ONSET

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: 12521011

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	Jan/11/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A
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090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

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:	Jan/11/2021
2.	Date of First Symptom Started:	Jan/6/2021
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Jan/10/2021

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

Symptoms - Other

5.	Symptoms - Other Text:	[]
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090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

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: 12521011

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.	Jan/6/2021	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages
2.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

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:	Jan/6/2021	Comments
2.	Specimen Type:	SWABBED MATERIAL	Comments
3.	Specimen Collection Location:	NASOPHARYNX	Comments
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	Comments
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST	Comments
6.	Trade Name:	ABBOTT MOLECULAR REALTIME SARS-COV-2 ASSAY	Comments
7.	Test Result:	NEGATIVE	Comments
8.	Comments/Findings/Details:	[ABBOTT ID NOW SARS COV-2, NAAT, ID NOW]	Comments
9.	Trade Name Other, Specify:	[]	Comments

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

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	Not Done _____ //	Comments
2	Specimen Type:	Not Done _____	Comments
3	Specimen Collection Location:	Not Done _____	Comments
4	Assay Code and Description:	Not Done _____	Comments
5	Device Type:	Not Done _____	Comments
6	Trade Name:	Not Done _____	Comments
7	Test Result:	Not Done _____	Comments
8	Comments/Findings/Details:	Not Done _____ []	Comments
9	Trade Name Other, Specify:	Not Done _____ []	Comments

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

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: 12521011

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_SELF
3.	Sample Collected?	YES Date of Collection: Jan/11/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[CV34600]
-----	-----------	-----------

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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: 12521011

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:	[Nasal swab sample collected at the hospital when he was admitted on 06Jan2021 per medical record.]

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
Jan/11/2021**Form:** HEALTH CARE UTILIZATION**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete, Frozen, Verified**Site No:** 1252**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family
Medicine**Subject No:** 12521011**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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: HOSPITALIZATION DETAILS

Form Version: 22-Apr-2020 21:02

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1.	HOSPITALIZATION STATUS	HOSPITAL	Jan/6/2021	NO Discharge Date: Jan/10/2021	Repeating Pages

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021

Form: HOSPITALIZATION DETAILS

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

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:	Jan/6/2021
4.	Ongoing?	NO Discharge Date: Jan/10/2021

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: 12521011

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	NON-INVASIVE POSITIVE PRESSURE VENTILATION	NON-INVASIVE POSITIVE PRESSURE VENTILATION	Jan/6/2021	Repeating Pages

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

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:	NON-INVASIVE POSITIVE PRESSURE VENTILATION
4.	Treatment:	[NON-INVASIVE POSITIVE PRESSURE VENTILATION]
5.	Start Date:	Jan/6/2021
6.	Ongoing?	NO End Date: Jan/10/2021

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021 **Form:** ILLNESS DETAILS
Form Version: 06-Jul-2020 21:52 **Form Status:** Data Complete, Frozen, Not Complete
Site No: 1252 **Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine
Subject No: 12521011 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

Illness Details		
1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [Pneumonia] Date of Diagnosis: Jan/6/2021
3.	Toxicity Grade:	2

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

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: 12521011

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.		Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

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

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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: 12521011

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
1.	CLINICAL CHEMISTRY	McLeod Loris Hospital 3612 Mitchell Street Loris SC 29569	Jan/6/2021	BLOOD	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					329	C Reactive Protein_PX329	[]	
					30	Alanine Aminotransferase_PX30	[]	
					28	Aspartate Aminotransferase_PX28	[]	
					35	Alkaline Phosphate_PX35	65	
					21	Bilirubin_PX21	0.5	
					47	Blood Urea Nitrogen_PX47	16	
					48	Creatinine_PX48	0.96	

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

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 3612 Mitchell Street Loris SC 29569]
3.	Collection Date:	Jan/6/2021
4.	Specimen Type:	BLOOD

Lab Result

5.a	Sponsor ID:	[329]
	Test:	C Reactive Protein_PX329
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.b	Sponsor ID:	[30]
	Test:	Alanine Aminotransferase_PX30
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.c	Sponsor ID:	[28]
	Test:	Aspartate Aminotransferase_PX28
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

5.d	Sponsor ID:	[35]
	Test:	Alkaline Phosphatase_PX35
	Result:	[65]
	Not Done:	
	LNMT	Low [50] High [250] Unit U/L
5.e	Sponsor ID:	[21]
	Test:	Bilirubin_PX21
	Result:	[0.5]
	Not Done:	
	LNMT	Low [0.1] High [1.2] Unit mg/dL
5.f	Sponsor ID:	[47]
	Test:	Blood Urea Nitrogen_PX47
	Result:	[16]
	Not Done:	
	LNMT	Low [9] High [20] Unit mg/dL

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

5.g	Sponsor ID:	[48]
	Test:	Creatinine_PX48
	Result:	[0.96]
	Not Done:	
	LNMT	Low [0.66] High [1.25] Unit mg/dL

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1252

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

Subject No: 12521011

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
1.	HEMATOLOGY	McLeod Loris Hospital 3612 Mitchell Street Loris SC 29569	Jan/6/2021	BLOOD	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					1	Hemoglobin_PX1	12.0	
					2	Hematocrit_PX2	36.2	
					3	Erythrocytes_PX3	[]	
					5	Platelets_PX5	214	
					7	Leukocytes_PX7	[]	
					608	Neutrophils_PX608	13.9	
					609	Eosinophils_PX609	0.0	
					612	Monocytes_PX612	0.9	
					610	Basophils_PX610	0.0	
					611	Lymphocytes_PX611	1.1	

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

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 3612 Mitchell Street Loris SC 29569]
3.	Collection Date:	Jan/6/2021
4.	Specimen Type:	BLOOD

Lab Result

5.a	Sponsor ID:	[1]
	Test:	Hemoglobin_PX1
	Result:	[12.0]
	Not Done:	
	LNMT	Low [14.0] High [18.0] Unit g/dL
5.b	Sponsor ID:	[2]
	Test:	Hematocrit_PX2
	Result:	[36.2]
	Not Done:	
	LNMT	Low [42.0] High [52.0] Unit %

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

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:	[214]
	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
5.f	Sponsor ID:	[608]
	Test:	Neutrophils_PX608
	Result:	[13.9]
	Not Done:	
	LNMT	Low [1.9] High [7.6] Unit 10^9/L

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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5.g	Sponsor ID:	[609]
	Test:	Eosinophils_PX609
	Result:	[0.0]
	Not Done:	
	LNMT	Low [0.00] High [0.50] Unit 10^9/L
5.h	Sponsor ID:	[612]
	Test:	Monocytes_PX612
	Result:	[0.9]
	Not Done:	
	LNMT	Low [0.2] High [1.5] Unit 10^9/L
5.i	Sponsor ID:	[610]
	Test:	Basophils_PX610
	Result:	[0.0]
	Not Done:	
	LNMT	Low [0.0] High [0.2] Unit 10^9/L

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

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

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: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details			Form Instance
1.	Jan/6/2021	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		1	140	62	

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

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Generated By: (b) (4)

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Vital Signs

1.	Date:	Jan/6/2021
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Vital Signs Details

2.a	Record Identifier:	1
	Systolic:	[140]
	Diastolic:	[62]
	Respiratory Rate in respirations/minute:	[20]
	Heart Rate in beats/minute:	[58]

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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: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details		Form Instance
1.	Jan/6/2021	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	47.0	

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

1.	Date:	Jan/6/2021
----	-------	------------

Vital Signs Details

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[47.0]

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: 12521011

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.	Jan/6/2021 17:40	83	0.30	Repeating Pages

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

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:	Jan/6/2021 17:40	Comments
2.	Arterial Blood Gases PaO2 (mmHg):	[83]	Comments
3.	FiO2 (Fraction of Inhaled Oxygen):	[0.30]	Comments

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: 12521011

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. DELETED	[]			Not Applicable	Not Applicable	Repeating Pages

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

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

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Concomitant Medications

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

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

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: 12521011

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.	Jan/6/2021	CHEST	X-RAY	ABNORMAL <i>If abnormal, specify findings:</i> Coarsened interstitium with nodular right lower lung density	Repeating Pages

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021 **Form:** IMAGING

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

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Imaging

1.	Date of Assessment:	Jan/6/2021
2.	Location of Assessment:	CHEST
3.	Type of Imaging Exam:	X-RAY
4.	Assessment:	ABNORMAL If abnormal, specify findings: [Coarsened interstitium with nodular right lower lung density]

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
on Feb/10/2021

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: 12521011

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	Feb/10/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A1
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090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit
on Feb/10/2021

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: 12521011

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	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/10/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPYY5K]
5.b	Sample ID	[BNWG75]
5.c	Sample ID	[BNWG74]

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1252

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

Subject No: 12521011

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: 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: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

Unplanned Assessments

1.	Assessments	
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Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1252

Subject No: 12521011

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/12/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

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

Disposition - Follow-Up

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1252

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

Subject No: 12521011

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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090177e196ae30e7\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: 12521011

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	[]
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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: 12521011

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	COPD exacerbation	Jan/6/2021 16:53	NO End Date Time: Jan/10/2021 10:10	Repeating Pages
2.	ADVERSE EVENT	2	Elevated Troponin	Jan/6/2021 16:53	NO End Date Time: Jan/10/2021 10:10	Repeating Pages
3.	ADVERSE EVENT	3	Sepsis	Jan/6/2021 16:53	NO End Date Time: Jan/10/2021 10:10	Repeating Pages
4. DELETED	ADVERSE EVENT	4	Pneumonia	Jan/6/2021 16:53	NO End Date Time: Jan/10/2021 10:10	Repeating Pages
5.	ADVERSE EVENT	5	Anemia	Jan/6/2021 16:53	NO End Date Time: Jan/10/2021 10:10	Repeating Pages
6.	ADVERSE EVENT	6	Hyperkalemia	Jan/6/2021 16:53	NO End Date Time: Jan/10/2021 10:10	Repeating Pages
7.	ADVERSE EVENT	7	Chronic Hypoxic respiratory failure	Jan/6/2021 16:53	NO End Date Time: Jan/10/2021 10:10	Repeating Pages
8.	ADVERSE EVENT	8	Low platelets	Jan/6/2021 16:53	NO End Date Time: Jan/10/2021 10:10	Repeating Pages
9.	ADVERSE EVENT	9	Low Lymphocytes	Jan/6/2021 16:53	NO End Date Time: Jan/10/2021 10:10	Repeating Pages

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Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

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Site No: 1252

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

Subject No: 12521011

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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

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

Subject Initials: ---

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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)	[COPD exacerbation]
4.	Start Date Time:	Jan/6/2021 16:53
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/10/2021 10:10
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event YES
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: [Increased shortness of breath]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

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

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	[2021015418]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT	Comments
2.	AE ID:	[2]	Comments
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Elevated Troponin]	Comments
4.	Start Date Time:	Jan/6/2021 16:53	Comments
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/10/2021 10:10	Comments
6.	Toxicity Grade:	2	Comments
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	Comments
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	Comments
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: [Heart problem]	Comments
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE	Comments
11.	Was a Concomitant Medication given?	NO	Comments
12.	Was a Non-Drug Treatment given?	NO	Comments

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED	Comments
14.	Did the adverse event cause the subject to be discontinued from the study?	NO	Comments
15.	Serious Adverse Event Number: For Pfizer Use Only	[]	Comments

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Not Complete

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)	[Sepsis]
4.	Start Date Time:	Jan/6/2021 16:53
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/10/2021 10:10
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: [Probably due to 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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

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	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted, Not 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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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Pneumonia]
4.	Start Date Time:	Jan/6/2021 16:53
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/10/2021 10:10
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: [Infection]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO

090177e196ae30e7\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: 12521011
Generated By: (b) (4)

Form: ADVERSE EVENT REPORT
Form Status: Data Complete, Deleted, Not Verified
Site Name: (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 18:51

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

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: 12521011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Anemia]
4.	Start Date Time:	Jan/6/2021 16:53
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/10/2021 10:10
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: [Probably due to anemia of chronic disease and without any symptoms of bleeding.]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

090177e196ae30e7\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: 12521011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

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

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	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

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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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Hyperkalemia]
4.	Start Date Time:	Jan/6/2021 16:53
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/10/2021 10:10
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: [Potassium level high in blood]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

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

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	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Not Complete

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:	[7]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Chronic Hypoxic respiratory failure]
4.	Start Date Time:	Jan/6/2021 16:53
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/10/2021 10:10
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: [Not enough of oxygen in the blood]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

090177e196ae30e7\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: 12521011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Not Complete

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

Subject Initials: ---

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

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	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

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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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[8]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Low platelets]
4.	Start Date Time:	Jan/6/2021 16:53
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/10/2021 10:10
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: [Low number of platelets in blood]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

090177e196ae30e7\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: 12521011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

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

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	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

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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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[9]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Low Lymphocytes]
4.	Start Date Time:	Jan/6/2021 16:53
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/10/2021 10:10
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: [Infection]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

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

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	[]

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: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

#	Category	Medication Error	Start Date	Is the medication error Still On going	Study Medication Errors Action	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

090177e196ae30e7\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: 12521011

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

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

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: 12521011

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	Repeating Pages

090177e196ae30e7\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: 12521011

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

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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: 12521011

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	Repeating Pages

090177e196ae30e7\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: 12521011

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

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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: 12521011

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	Repeating Pages

090177e196ae30e7\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: 12521011

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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[eCRF Audit Trail History](#)

Radiation Treatment

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

090177e196ae30e7\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: 12521011 **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	Repeating Pages

090177e196ae30e7\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: 12521011

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 _____	Comments
2.	Date of Transfusion:	Not Applicable _____ //	Comments

Header Text: c4591001

Visit: Unplanned Vaccination - 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: 12521011

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: 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: 12521011

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 Version: 10-Dec-2020 02:26

Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: VACCINATION

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

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?	

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form Version: 10-Oct-2020 15:57

Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: CONTACT OUTCOME - MONTH 1

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

Contact Outcome

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form Version: 10-Oct-2020 16:01

Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: CONTACT OUTCOME - MONTH 6

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

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: 12521011

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: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

Informed Consent - Asymptomatic Surveillance

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

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

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: 12521011

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	[]
----	-----------	-----

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: 12521011

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	[]
----	-----------	-----

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

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	Jan/12/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2
----	---	--

090177e196ae30e7\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: 12521011

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/12/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1252

Subject No: 12521011

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 _____ //	Comments

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1252

Subject No: 12521011

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

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

Death Details

1.	Date of Collection / Notification of Death:	Not Applicable _____ //	Comments
----	---	-------------------------------	--------------------------

Cause of Death

2.	Cause of Death Status:	Not Applicable _____
	Cause of Death:	Not Applicable _____ []

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1252

Subject No: 12521011

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	FOLLOW-UP
2.	Subject Status Date	Oct/12/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1252

Subject No: 12521011

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 Version: 22-Apr-2020 21:04

Site No: 1252

Subject No: 12521011

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

[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-10-2021 16:29:06 (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.

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1252

Subject No: 12521011

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: ---

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Form	Aug-21-2020 06:26:16 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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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: 12521011

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Form	Jan-11-2021 14:41:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable Not Applicable

Header Text: c4591001

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Site No: 1252

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1	Jan-11-2021 14:41:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable Not Applicable

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2	Jan-11-2021 14:41:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable Not Applicable

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5	Jan-11-2021 14:41:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable Not Applicable

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6	Jan-11-2021 14:41:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable Not Applicable

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7	Jan-11-2021 14:41:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable Not Applicable

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8	Jan-11-2021 14:41:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable Not Applicable

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9	Jan-11-2021 14:41:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable Not Applicable

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Form	Jan-18-2021 08:44:05 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Duplicate

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Site No: 1252

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Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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Form	Jan-15-2021 09:44:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable Not Applicable
Form	Jan-15-2021 09:38:45 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Transcription error

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1	Jan-15-2021 09:44:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable Not Applicable

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2	Jan-15-2021 09:44:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable Not Applicable
2	Jan-15-2021 09:38:15 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Transcription error

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Generated By: (b) (4)

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3	Jan-15-2021 09:44:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable Not Applicable

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4	Jan-15-2021 09:44:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable Not Applicable
4	Jan-15-2021 09:39:14 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Transcription error

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5	Jan-15-2021 09:44:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable Not Applicable

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6	Jan-15-2021 09:44:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable Not Applicable

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7	Jan-15-2021 09:44:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable Not Applicable

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8	Jan-15-2021 09:44:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable Not Applicable

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9	Jan-15-2021 09:44:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable Not Applicable

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10	Jan-15-2021 09:44:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable Not Applicable

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11	Jan-19-2021 15:51:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
11	Jan-15-2021 09:44:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable Not Applicable

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12	Jan-19-2021 15:51:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
12	Jan-15-2021 09:44:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable Not Applicable

Header Text: c4591001

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13	Jan-19-2021 15:51:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
13	Jan-15-2021 09:44:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable Not Applicable

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14	Jan-19-2021 15:51:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
14	Jan-15-2021 09:44:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable Not Applicable

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15	Jan-19-2021 15:51:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
15	Jan-15-2021 09:44:21 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable
			Not Applicable

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Subject No: 12521011

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Form: MEDICATION ERROR - Comments

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Site No: 1252

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6	Jan-08-2021 10:30:47 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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8	Jan-08-2021 10:30:47 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Generated By: (b) (4)

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Subject No: 12521011

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - 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
6	Jan-08-2021 10:31:48 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae30e7\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: 12521011

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - 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
7	Jan-08-2021 10:31:48 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - 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
8	Jan-08-2021 10:31:48 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae30e7\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: 12521011

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - 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
9	Jan-08-2021 10:31:48 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - 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
10	Jan-08-2021 10:31:48 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae30e7\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: 12521011

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: ---

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

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Item	Date	User	Comment
Form	Jan-08-2021 10:32:08 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae30e7\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: 12521011

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: ---

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

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Item	Date	User	Comment
1	Jan-08-2021 10:32:08 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae30e7\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: 12521011

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: ---

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

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Item	Date	User	Comment
2	Jan-08-2021 10:32:08 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1252

Subject No: 12521011

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: ---

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

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Item	Date	User	Comment
3	Jan-08-2021 10:32:08 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1252

Subject No: 12521011

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: ---

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

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Item	Date	User	Comment
4	Jan-08-2021 10:32:08 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1252

Subject No: 12521011

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: ---

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

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Item	Date	User	Comment
5	Jan-08-2021 10:32:08 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae30e7\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: 12521011

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: ---

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

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Item	Date	User	Comment
6	Jan-08-2021 10:32:08 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: TRANSFUSIONS - 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-08-2021 10:32:23 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae30e7\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: 12521011

Generated By: (b) (4)

Form: TRANSFUSIONS - 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	Jan-08-2021 10:32:23 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: TRANSFUSIONS - 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
2	Jan-08-2021 10:32:23 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1252

Subject No: 12521011

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	Feb-15-2021 14:45:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Disposition

Form Version: 22-Apr-2020 21:03

Site No: 1252

Subject No: 12521011

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
1	Feb-15-2021 14:45:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae30e7\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: 12521011

Generated By: (b) (4)

Form: DEATH DETAILS CODED - 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	Feb-15-2021 14:46:15 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Disposition

Form Version: 22-Apr-2020 21:03

Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: DEATH DETAILS CODED - 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-15-2021 14:46:15 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae30e7\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: 12521011

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-10-2021 16:29:06 (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	Mar-10-2021 15:47:16 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Stephen Grubb	Approved	Mar-03-2021 12:07:51 (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-26-2021 13:27:56 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Stephen Grubb	Approved	Feb-24-2021 16:22:48 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae30e7\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: 12521011

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.

Debra Scotti	N/A	Feb-18-2021 09:27:11 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Stephen Grubb	Approved	Feb-16-2021 16:03:05 (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-15-2021 14:45:41 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Stephen Grubb	Approved	Feb-12-2021 14:23:20 (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 10:42:25 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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090177e196ae30e7\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:** 12521011**Generated By:** (b) (4)**Form:** CASEBOOK SIGNATURE FORM - Signature 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**Affidavit:**

N/A

Stephen Grubb	Approved	Feb-09-2021 11:55:47 (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-09-2021 08:15:52 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Stephen Grubb	Approved	Jan-29-2021 09:14:33 (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-25-2021 03:39:20 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Stephen Grubb	Approved	Jan-24-2021 13:46:48 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1252

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

Subject No: 12521011

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-18-2021 08:43:05 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Stephen Grubb	Approved	Jan-15-2021 11:23:31 (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-12-2021 16:47:08 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Stephen Grubb	Approved	Jan-11-2021 17:01:43 (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-08-2021 10:30:27 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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090177e196ae30e7\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: 12521011

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - Signature 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

Affidavit:

N/A

Stephen Grubb	Approved	Oct-21-2020 17:19:17 (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: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1252

Subject No: 12521011

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 22:31:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-17-2020 22:31:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1252

Subject No: 12521011

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 22:32:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Aug/17/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1252

Subject No: 12521011

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 22:31:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12521011	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-17-2020 22:31:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1935	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-17-2020 22:32:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-17-2020 22:32:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR O F SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-17-2020 22:32:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae30e7\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: 12521011

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
Aug-26-2020 09:38:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	As per the update.
Aug-25-2020 17:47:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Aug-21-2020 11:10:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	IVRS Reconciliation: Randomization date and randomization number recorded at Impala but not recorded at Inform. Please review and update data as appropriate. Else, clarify. Thank you.
Aug-17-2020 22:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/17/2020	Initial Entry

090177e196ae30e7\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: 12521011

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 06:26:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/17/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-21-2020 06:26:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-21-2020 06:26:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae30e7\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: 12521011
 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
Aug-25-2020 17:31:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Anxiety Start Date: Mar/4/2019 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 17:31:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 17:31:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Anxiety	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 17:31:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/4/2019	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 17:31:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.b

Date	Location	User	Value	Reason
Aug-25-2020 17:32:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2	Initial Entry

090177e196ae30e7\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: 12521011

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

			Medical History Chronic obstructive lung disease	
			Term: UNK/UNK/2010	
			Start Date: YES	
			Ongoing:	

090177e196ae30e7\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: 12521011

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

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 17:32:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-31-2020 08:22:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Aug-28-2020 21:32:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Aug-27-2020 11:27:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Opened	GPD Clin: Per IC3, please confirm stability of symptoms prior to study enrolment; that no significant change in therapy or hospitalization for worsening of disease within 6 weeks of enrolment. Also, confirm EC13 reviewed (systemic corticosteroid use)
Aug-25-2020 17:32:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Chronic obstructive lung disease	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 17:32:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 17:32:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30e7\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: 12521011

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

I.c

Date	Location	User	Value	Reason
Aug-25-2020 17:41:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term Insomnia : Start Date: UNK/UNK/2015 Ongoing: YES	Initial Entry

I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 17:41:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 17:41:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Insomnia	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 17:41:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 17:41:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-25-2020 17:42:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: Depression Start Date: Apr/9/2018	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1252

Subject No: 12521011

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

			Ongoing:	YES	
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I.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 17:42:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 17:42:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Depression	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 17:42:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Apr/9/2018	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 17:42:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Aug-25-2020 17:43:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term Hypogonadism : Start Date: UNK/UNK/2016 Ongoing: YES	Initial Entry

090177e196ae30e7\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: 12521011

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

1.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 17:43:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 17:43:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hypogonadism	Initial Entry

1.e Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 17:43:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2016	Initial Entry

1.e Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 17:43:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

1.f

Date	Location	User	Value	Reason
Sep-15-2020 16:25:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 6 Medical History Term: Osteoarthritis in back Start Date: UNK/UNK/2009 Ongoing: YES	New Information
Aug-25-2020 17:44:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History Term: Osteoarthritis Start Date: UNK/UNK/2009 Ongoing: YES	Initial Entry

090177e196ae30e7\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: 12521011

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

If Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 17:44:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

If Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-16-2020 09:08:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-15-2020 16:25:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Sep-15-2020 16:25:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Osteoarthritis in back	New Information
Sep-14-2020 17:05:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Please specify body site location in the medical history term Osteoarthritis. Thank you.
Aug-25-2020 17:44:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Osteoarthritis	Initial Entry

If Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 17:44:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2009	Initial Entry

If Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 17:44:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.g

Date	Location	User	Value	Reason
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090177e196ae30e7\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: 12521011

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

Aug-25-2020 17:44:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 7 Medical History Term Gerd : Start Date: UNK/UNK/2008 Ongoing: YES	Initial Entry
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I.g Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 17:44:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 17:44:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Gerd	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 17:44:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2008	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 17:44:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.h

Date	Location	User	Value	Reason
Aug-25-2020 17:45:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 8 Medical History Term: Benign Prostatic Hypertrophy Start Date: UNK/UNK/2017 Ongoing: YES	Initial Entry

090177e196ae30e7\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: 12521011

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

I.h Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 17:45:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 17:45:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Benign Prostatic Hyperplasia	Initial Entry

I.h Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 17:45:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2017	Initial Entry

I.h Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 17:45:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.i

Date	Location	User	Value	Reason
Sep-14-2020 15:49:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 9 Medical History Te rm: Coronary artery dis ease Start Date: Apr/UNK/2018 Ongoing: YES	Initial Entry
Sep-14-2020 15:49:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 9 Medical History Te rm: Coronary artery dis ease Start Date: Apr/UNK/2018 Ongoing:	Initial Entry

090177e196ae30e7\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: 12521011

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>I.i</i>				
Date	Location	User	Value	Reason
Sep-14-2020 15:42:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: Medical History Term: Start Date: Ongoing:	Transcription Error
Sep-14-2020 08:30:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: Medical History Term: Start Date: Ongoing:	Duplicate data (DELETED)
Sep-14-2020 08:29:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History Term: Start Date: Ongoing:	Duplicate
Sep-10-2020 10:27:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 9 Medical History Term: Stented Coronary Artery heart disease Start Date: Apr/UNK/2018 Ongoing: NO End Date: Apr/UNK/2018	Heart disease
Aug-25-2020 17:46:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 9 Medical History Term: Stented Coronary Artery Start Date: Apr/UNK/2018 Ongoing: NO End Date: Apr/UNK/2018	Initial Entry

090177e196ae30e7\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: 12521011

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

Li Line/MH Number:

Date	Location	User	Value	Reason
Sep-14-2020 15:49:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry
Sep-14-2020 15:42:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-14-2020 08:30:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Duplicate data (DELETED)
Sep-14-2020 08:29:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Duplicate
Aug-25-2020 17:46:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

Li Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-14-2020 16:10:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Closed	Response satisfies query
Sep-14-2020 15:49:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Sep-14-2020 15:49:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Coronary artery disease	Initial Entry
Sep-14-2020 15:42:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-14-2020 15:12:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Reissued:Opened	CLINQUERY: Query closed as 'duplicate' but line entry previously reported coronary artery stent, now deleted. Line below reports angioplasty. Please review data change per prior queries.

090177e196ae30e7\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: 12521011

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

Sep-14-2020 08:30:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Duplicate data (DELETED)
Sep-14-2020 08:29:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Duplicate
Sep-14-2020 08:29:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Duplicate
Sep-14-2020 06:20:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Reissued:Opened	CLINQUERY: Type of heart disease or related condition to coronary artery stent/angioplasty not captured in CRF. Please clarify, add as a separate line entry
Sep-11-2020 10:11:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Sep-11-2020 06:58:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Reissued:Opened	CLINQUERY: Please clarify the type of heart disease (eg CAD?) and move into a separate line entry. Review if ongoing.
Sep-10-2020 10:27:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Heart disease
Sep-10-2020 10:27:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Stented Coronary Artery heart disease	Heart disease
Sep-02-2020 08:22:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Please review if the underlying condition should be reported as a separate entry in the MH listing
Sep-02-2020 08:00:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (b) (4)	Query 1: Candidate	CLINQUERY: Please review if the underlying condition should be reported as a separate entry in the MH listing
Aug-25-2020 17:46:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Stented Coronary Artery	Initial Entry

090177e196ae30e7\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: 12521011

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

I.i Start Date:

Date	Location	User	Value	Reason
Sep-14-2020 15:49:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Apr/UNK/2018	Initial Entry
Sep-14-2020 15:42:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-14-2020 08:30:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Duplicate data (DELETED)
Sep-14-2020 08:29:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Duplicate
Aug-25-2020 17:46:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Apr/UNK/2018	Initial Entry

I.i Ongoing:

Date	Location	User	Value	Reason
Sep-14-2020 15:49:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
Sep-14-2020 15:42:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Sep-14-2020 08:30:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Duplicate data (DELETED)
Sep-14-2020 08:29:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Duplicate
Aug-25-2020 17:46:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Apr/UNK/2018	Initial Entry

I.j

Date	Location	User	Value	Reason
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090177e196ae30e7\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: 12521011

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

Sep-11-2020 10:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 10 Medical History Term: Angioplasty Start Date: Apr/9/2018 Ongoing: NO End Date: Apr/9/2018	Initial Entry
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1.j Line/MH Number:

Date	Location	User	Value	Reason
Sep-11-2020 10:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

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

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

1.j Start Date:

Date	Location	User	Value	Reason
Sep-11-2020 10:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Apr/9/2018	Initial Entry

1.j Ongoing:

Date	Location	User	Value	Reason
Sep-11-2020 10:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Apr/9/2018	Initial Entry

090177e196ae30e7\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: 12521011

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

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1. Date:

Date	Location	User	Value	Reason
Aug-25-2020 17:20:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/17/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-25-2020 17:20:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 140.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-25-2020 17:20:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-25-2020 17:20:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 68.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-25-2020 17:20:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-25-2020 17:20:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 21.3	Initial Entry

7.a

Date	Location	User	Value	Reason
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090177e196ae30e7\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: 12521011

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

Aug-25-2020 17:20:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 97.2 Temperature Unit: F Temperature Location ORAL CAVIT :: Y	Initial Entry
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7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-25-2020 17:20:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-25-2020 17:20:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.2	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-25-2020 17:20:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-25-2020 17:20:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae30e7\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: 12521011

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-25-2020 17:21:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/17/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-25-2020 17:21:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 230752	Initial Entry

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1252
Subject No: 12521011
Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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. Data Origin

Date	Location	User	Value	Reason
Aug-21-2020 06:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-21-2020 06:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-21-2020 06:27:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-21-2020 06:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-21-2020 06:27:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-21-2020 06:27:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNWG1M	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 06:27:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNWG1M	Initial Entry

Header Text: c4591001
 Visit: V1_DAY1_VAX1_L
 Form Version: 22-Apr-2020 21:03
 Site No: 1252
 Subject No: 12521011
 Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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

5.b

Date	Location	User	Value	Reason
Aug-21-2020 06:27:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNWG1N	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 06:27:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNWG1N	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-21-2020 06:27:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPYXM3	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 06:27:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPYXM3	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-21-2020 06:28:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPYXM4	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 06:28:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPYXM4	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-21-2020 06:28:48 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae30e7\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: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)		(b) (4)	Sample ID: BPYXM5	
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5.e Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 06:28:48 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPYXM5	Initial Entry

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1252
Subject No: 12521011
Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - 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. Data Origin

Date	Location	User	Value	Reason
Aug-21-2020 06:29:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-21-2020 06:29:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-21-2020 06:29:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-21-2020 06:29:34 (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 06:29:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Aug/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-21-2020 06:29:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPYXLT	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 06:29:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPYXLT	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1252

Subject No: 12521011

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 17:19:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-25-2020 17:19:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-25-2020 17:19:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-25-2020 17:19:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aug/17/2020 16:50	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-25-2020 17:19:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-25-2020 17:19:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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090177e196ae30e7\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: 12521011

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

Aug-25-2020 17:19:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-25-2020 17:19:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Aug-25-2020 17:19:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30e7\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: 12521011

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
Aug-24-2020 21:09:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

090177e196ae30e7\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: 12521011

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
Sep-09-2020 11:05:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/9/2020	Initial Entry

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 21-Aug-2020 02:51**Site No:** 1252**Subject No:** 12521011**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[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Sep-09-2020 15:52:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/9/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-09-2020 15:52:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 97.8 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-09-2020 15:52:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-09-2020 15:52:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.8	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-09-2020 15:52:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-09-2020 15:52:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ORAL CAVITY	Initial Entry

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1252**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family Medicine**Subject No:** 12521011**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
Sep-09-2020 11:05:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-09-2020 11:05:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-09-2020 11:05:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-09-2020 11:05:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-09-2020 11:05:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/9/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-09-2020 11:05:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPYXZ7	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-09-2020 11:05:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPYXZ7	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1252

Subject No: 12521011

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-09-2020 15:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-09-2020 15:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-09-2020 15:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-09-2020 15:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/9/2020 09:40	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-09-2020 15:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-09-2020 15:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
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090177e196ae30e7\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: 12521011

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

Sep-09-2020 15:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
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10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-09-2020 15:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-09-2020 15:54:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae30e7\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: 12521011

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-12-2020 10:27:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/12/2020	Initial Entry

090177e196ae30e7\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:** 12521011**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
Oct-12-2020 10:27:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-12-2020 10:27:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-12-2020 13:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-12-2020 10:27:22 (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-12-2020 10:27:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/12/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-12-2020 13:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPYY3H	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-12-2020 13:23:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPYY3H	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

5.b

Date	Location	User	Value	Reason
Oct-12-2020 13:23:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPYY3J	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-12-2020 13:23:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPYY3J	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-12-2020 13:24:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPYY3K	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-12-2020 13:24:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPYY3K	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-12-2020 13:24:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNWG4X	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Oct-12-2020 13:24:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNWG4X	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-12-2020 13:24:42 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

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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: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)		(b) (4)	Sample ID: BNWG4Y	
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5.e Sample ID

Date	Location	User	Value	Reason
Oct-12-2020 13:24:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNWG4Y	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: DATE OF VISIT - 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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I. Date of Visit

Date	Location	User	Value	Reason
Mar-10-2021 15:47:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/10/2021	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001**Visit:** V4_MONTH6_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Verified**Site No:** 1252**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family
Medicine**Subject No:** 12521011**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
Mar-10-2021 16:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-10-2021 16:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-10-2021 16:09:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-10-2021 16:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-10-2021 16:09:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/10/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-10-2021 16:09:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPYY6P	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-10-2021 16:09:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPYY6P	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

5.b

Date	Location	User	Value	Reason
Mar-10-2021 16:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNWG88	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-10-2021 16:10:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNWG88	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-10-2021 16:10:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNWG89	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-10-2021 16:10:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNWG89	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021**Form:** DATE OF VISIT - ILLNESS ONSET - 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:** 12521011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Date of Visit**

Date	Location	User	Value	Reason
Jan-11-2021 14:41:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-11-2021 14:40:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jan-11-2021 14:39:26 (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.
Jan-11-2021 14:39:26 (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.
Jan-11-2021 14:39:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/11/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Jan-11-2021 14:39:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021**Form Version:** 10-Dec-2020 02:29**Site No:** 1252**Subject No:** 12521011**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Jan-11-2021 14:58:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-11-2021 14:40:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	All symptoms are reported as Not Present and there is no Other Symptom reported. Please review and update as appropriate.
Jan-11-2021 14:40:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/11/2021	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Jan-11-2021 14:40:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Jan-11-2021 14:40:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Jan/10/2021	Initial Entry

4.a

Date	Location	User	Value	Reason
Jan-11-2021 14:40:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Jan-11-2021 14:40:36	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021**Form Version:** 10-Dec-2020 02:29**Site No:** 1252**Subject No:** 12521011**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - 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

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	FEVER	
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4.a Was symptom present?

Date	Location	User	Value	Reason
Jan-11-2021 14:40:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Jan-11-2021 14:40:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: NO	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Jan-11-2021 14:40:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Jan-11-2021 14:40:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Jan-11-2021 14:58:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED S HORTNESS OF BREATH Symptom Present: YES	Transcription Error
Jan-11-2021 14:40:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED S HORTNESS OF BREATH Symptom Present: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

4.c Symptoms:

Date	Location	User	Value	Reason
Jan-11-2021 14:40:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Jan-11-2021 14:58:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Transcription Error
Jan-11-2021 14:40:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Jan-11-2021 14:40:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Jan-11-2021 14:40:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Jan-11-2021 14:40:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Jan-11-2021 14:40:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom Present: NO	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

4.e Symptoms:

Date	Location	User	Value	Reason
Jan-11-2021 14:40:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Jan-11-2021 14:40:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Jan-11-2021 14:40:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW LOSS OF TASTE OR SMELL Symptom Present: NO	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Jan-11-2021 14:40:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Jan-11-2021 14:40:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Jan-11-2021 14:40:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED SORE THROAT Symptom Present: NO	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

4.g Symptoms:

Date	Location	User	Value	Reason
Jan-11-2021 14:40:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Jan-11-2021 14:40:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Jan-11-2021 14:40:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Jan-11-2021 14:40:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Jan-11-2021 14:40:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Jan-11-2021 14:40:36 (UTC 05 00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: VOMITING Symptom Present: NO	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

4.i Symptoms:

Date	Location	User	Value	Reason
Jan-11-2021 14:40:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Jan-11-2021 14:40:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021

Form: MICROBIOLOGY SPECIMEN - Audit Trail

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: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Jan-13-2021 14:52:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	
Jan-13-2021 14:49:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Undeleted	Transcription Error
Jan-13-2021 14:49:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Jan-13-2021 14:48:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Undeleted	Transcription Error
Jan-13-2021 14:46:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	New Information
Jan-13-2021 14:46:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Undeleted	New Information
Jan-12-2021 16:47:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	New Information

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021

Form: MICROBIOLOGY SPECIMEN - Audit Trail

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: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Jan-18-2021 08:54:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Undeleted	Transcription Error
Jan-18-2021 08:48:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Jan-18-2021 08:46:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Undeleted	Transcription Error
Jan-18-2021 08:45:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Jan-18-2021 08:44:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Undeleted	Transcription Error
Jan-18-2021 08:43:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Jan-12-2021 16:50:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

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I. Actual Date of Collection:

Date	Location	User	Value	Reason
Jan-17-2021 23:39:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Jan-13-2021 14:52:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021	Initial Entry
Jan-13-2021 14:50:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-13-2021 14:46:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Jan-13-2021 14:19:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Clin: Please enter all the information available on this CRF MICROBIOLOGY SPECIMEN page (date, type of assay....)
Jan-13-2021 11:59:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Reissued:Candidate	Clin: Please enter all the information available on this CRF MICROBIOLOGY SPECIMEN page (date, type of assay....)
Jan-12-2021 16:45:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Kit used was SARS COV-2, NAAT, ID NOW
Jan-12-2021 16:36:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: It was stated that a Covid-19 test was completed on 06Jan2021 at the hospital and the kit used was SARS COV-2, NAAT, ID NOW. Please enter this information available on this form
Jan-11-2021 14:41:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

2. Specimen Type:

Date	Location	User	Value	Reason
Jan-13-2021 14:52:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWABBED MATERIAL	Initial Entry
Jan-13-2021 14:50:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-11-2021 14:41:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Jan-13-2021 14:52:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NASOPHARYNX	Initial Entry
Jan-13-2021 14:50:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-11-2021 14:41:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Jan-13-2021 14:52:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	Initial Entry
Jan-13-2021 14:50:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-11-2021 14:41:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Jan-13-2021 14:52:16 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)				
Jan-13-2021 14:50:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-11-2021 14:41:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Jan-18-2021 09:14:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ABBOTT MOLECULAR REALTIME SARS-COV-2 ASSAY	Initial Entry
Jan-18-2021 08:58:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-18-2021 08:58:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jan-18-2021 08:56:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Trade Name is Other, however Trade Name Other, Specify is not completed. Please update.
Jan-13-2021 14:52:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry
Jan-13-2021 14:50:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-11-2021 14:41:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Jan-13-2021 14:52:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry
Jan-13-2021 14:50:29 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)		(b) (4)		
Jan-11-2021 14:41:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Jan-18-2021 09:14:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ABBOTT ID NOW SARS COV-2, NA AT, ID NOW	Initial Entry
Jan-18-2021 09:13:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jan-18-2021 09:00:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Kit used in hospital SARS COV-2, NA AT, ID NOW. Trade name not available in hospital medical records.	New Information
Jan-13-2021 14:52:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Kit used in hospital SARS COV-2, NA AT, ID NOW	Initial Entry
Jan-13-2021 14:50:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-11-2021 14:41:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Jan-19-2021 02:44:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-18-2021 08:56:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-18-2021 08:56:36 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

Eastern Time (US & Canada)				
Jan-18-2021 04:49:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	sars cov 2, naat, id now is not indicated on the FDA cleared (including Emergency Use Authorization) diagnostic list and is not indicated as CLIA certified lab or ISO 15189 accredited lab . Please verify and update as appropriate. Otherwise, please provide clarification. (b) (4)
Jan-13-2021 14:52:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SARS COV-2, N AAT, ID NOW	Initial Entry
Jan-13-2021 14:50:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-11-2021 14:41:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

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-18-2021 08:52:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Jan-18-2021 08:47:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jan-12-2021 16:50:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Jan-18-2021 08:52:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Jan-18-2021 08:47:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jan-12-2021 16:50:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWABBED MATERIAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Jan-18-2021 08:52:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Jan-18-2021 08:47:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jan-12-2021 16:50:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
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090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

Jan-18-2021 08:52:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Done	Initial Entry
Jan-18-2021 08:47:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Jan-12-2021 16:50:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Jan-18-2021 08:52:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Done	Initial Entry
Jan-18-2021 08:47:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Jan-12-2021 16:50:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Jan-18-2021 08:52:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Jan-18-2021 08:48:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Jan-18-2021 08:48:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jan-18-2021 08:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Trade Name is Other, however Trade Name Other, Specify is not completed. Please update.
Jan-12-2021 16:50:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen, Verified**Site No:** 1252**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family
Medicine**Subject No:** 12521011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51

Jan-12-2021 16:50:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Trade Name is Other, however Trade Name Other, Specify is not completed. Please update.
Jan-12-2021 16:50:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Jan-18-2021 08:52:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Jan-18-2021 08:47:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jan-12-2021 16:50:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Jan-18-2021 08:52:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Jan-18-2021 08:47:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jan-12-2021 16:50:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SARS COV-2, NAAT, ID NOW	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Jan-19-2021 05:17:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-18-2021 08:52:10	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-05:00) Eastern Time (US & Canada)				
Jan-18-2021 08:47:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jan-18-2021 08:43:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-18-2021 07:37:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	sars cov 2, naat, id now is not indicated on the FDA cleared (including Emergency Use Authorization) diagnostic list and is not indicated as CLIA certified lab or ISO 15189 accredited lab . Please verify and update as appropriate. Otherwise, please provide clarification. (b) (4)
Jan-12-2021 16:50:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SARS COV-2, N AAT, ID NOW	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021
Form Version: 22-Apr-2020 21:03
Site No: 1252
Subject No: 12521011
Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - 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
Jan-11-2021 14:41:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-11-2021 14:41:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-11-2021 14:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-11-2021 14:41:46 (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.
Jan-11-2021 14:41:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Jan/11/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-11-2021 14:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: CV34600	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-11-2021 14:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CV34600	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

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
Jan-11-2021 14:44:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-11-2021 14:44:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-11-2021 14:44:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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-11-2021 14:44:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nasal swab sample collected at the hospital when he was admitted on 06Jan2021 per medical record.	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

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
Jan-11-2021 14:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-11-2021 14:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-11-2021 14:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Jan-11-2021 14:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

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
Jan-11-2021 14:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-11-2021 14:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

I.c

Date	Location	User	Value	Reason
Jan-11-2021 14:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-11-2021 14:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-11-2021 14:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

I.d

Date	Location	User	Value	Reason
Jan-11-2021 14:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGENT CARE	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

			Occurrence of Visits or Contacts:	NO
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1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-11-2021 14:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-11-2021 14:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Jan-11-2021 14:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-11-2021 14:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-11-2021 14:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Jan-11-2021 14:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTHER	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

			Occurrence of Visits or Cont NO acts:	
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1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-11-2021 14:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-11-2021 14:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

3. Has the subject been hospitalized due to potential COVID-19 illness?

Date	Location	User	Value	Reason
Jan-13-2021 11:46:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Jan-12-2021 16:56:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Has the subject been in intensive care due to potential COVID-19 illness? NO	New Information
Jan-12-2021 16:51:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-12-2021 16:51:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Transcription Error
Jan-12-2021 16:38:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: The subject was hospitalized for "Chronic obstructive pulmonary disease exacerbation" please update as "YES"
Jan-11-2021 14:45:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021

Form: HOSPITALIZATION DETAILS - Audit Trail

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: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Jan-12-2021 16:56:48 (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 Jan/11/2021

Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

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
Jan-12-2021 16:56:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HOSPITALIZATION STATUS	Initial Entry

2. Hospitalization Term:

Date	Location	User	Value	Reason
Jan-12-2021 16:56:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HOSPITAL	Initial Entry

3. Admission Date:

Date	Location	User	Value	Reason
Jan-13-2021 13:14:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-13-2021 13:03:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021	Initial Entry
Jan-13-2021 13:02:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Subject was not hospitalized because of Covid-19. The subject has SOB (COPD Exacerbation). A nasal swab was collected at the hospital and it was negative.
Jan-13-2021 13:02:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Subject was not hospitalized because of Covid-19. The subject has SOB (COPD Exacerbation). A nasal swab was collected at the hospital and it was negative.
Jan-13-2021 10:50:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLIQUERY: Hospitalization: This subject had COVID-19 Illness and was hospitalized. Please enter any available

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

				information (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...). Please make every effort to obtain these information.
Jan-12-2021 16:56:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021	Initial Entry

4. Ongoing?

Date	Location	User	Value	Reason
Jan-12-2021 16:56:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Discharge Date: Jan/10/2021	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021

Form: RESPIRATORY TREATMENT - Audit Trail

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: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Jan-11-2021 14:50:58 (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
Jan/11/2021

Form: RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

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
Jan-11-2021 14:50:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Jan-11-2021 14:50:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: YES	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Jan-11-2021 14:50:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NON-INVASIVE POSITIVE PRESSU RE VENTILATION	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Jan-11-2021 14:50:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NON-INVASIVE POSITIVE PRESSUR E VENTILATION	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Jan-11-2021 14:50:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Jan-11-2021 14:50:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: Jan/10/2021	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Not Complete

Site No: 1252

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

Subject No: 12521011

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
Jan-11-2021 14:54:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Mar-04-2021 11:41:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 3: Closed	Response satisfies query
Mar-03-2021 08:37:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Changed Information
Mar-03-2021 08:37:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Respiratory Illness Diagnosis:</i> Pneumonia Date of Diagnosis: Jan/6/2021	Changed Information
Mar-03-2021 02:30:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	Thanks for the response, form has been unfreeze, please update as per below query
Mar-02-2021 15:22:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Closed	Response satisfies query
Mar-02-2021 15:18:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 3: Reissued:Candidate	Clin: Please unfreeze so that the query can be answered
Feb-26-2021 13:29:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Feb-26-2021 10:52:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Please unfreeze so that the query can be answered

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021**Form:** ILLNESS DETAILS - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:52**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1252**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family
Medicine**Subject No:** 12521011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51

Feb-25-2021 16:47:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 3: Opened	Clin: Please consider in response to "Was a diagnosis obtained for Potential COVID-19 Illness" entering "Pneumonia" instead of "Chronic obstructive pulmonary disease exacerbation"
Feb-25-2021 16:46:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Opened	Clin: Per Prot Sect 8.3.7., COVID-19 related COVID-19 PNEUMONIA does not qualify as AE and please should be documented only on the COVID-19 CRF ILLNESS DETAILS form ONLY as PNEUMONIA and should not be captured on the AE CRF page.
Jan-13-2021 11:13:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Jan-12-2021 16:54:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Jan-12-2021 16:54:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Respiratory Illness Diagnosis:</i> Chronic obstructive pulmonary disease exacerbation Date of Diagnosis: Jan/6/2021	New Information
Jan-12-2021 16:39:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Please consider in response to "Was a diagnosis obtained for Potential COVID-19 Illness" entering "Chronic obstructive pulmonary disease exacerbation"

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Not Complete

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

Jan-11-2021 14:54:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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3. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-11-2021 14:54:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021

Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

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2. Subcategory of Clinical Event:

Date	Location	User	Value	Reason
Jan-11-2021 15:00:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

3. Was a diagnosis obtained?

Date	Location	User	Value	Reason
Jan-11-2021 15:00:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

4. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-11-2021 15:01:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021

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: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

Form Version: 21-Aug-2020 02:49

Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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. Lab Panel:

Date	Location	User	Value	Reason
Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: CLINICAL CHEMISTRY	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: McLeod Loris Hospital 3612 Mitchell Street Loris SC 29569	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id 329 entifier: Test:: C Reactive Protein _PX329 Result:: Not Done:: NOT DONE Lab Normal Range :	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
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090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 329	Initial Entry
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5.a Test:

Date	Location	User	Value	Reason
Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C Reactive Protein_PX329	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 30 Test:: Alanine Aminotransf erase_PX30 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sponsor ID:

Date	Location	User	Value	Reason
Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Alanine Aminotransferase_PX30	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 28 Test:: Aspartate Aminotransferase_PX28 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF 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: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sponsor ID:

Date	Location	User	Value	Reason
Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 28	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aspartate Aminotransferase_PX28	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined I 35 dentifier: Test:: Alkaline Phosphata se_PX35 Result:: 65 Not Done:: Lab Normal Rang <i>Low</i> e: 50 <i>High</i> 250 <i>Unit</i> U/L	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021**Form Version:** 21-Aug-2020 02:49**Site No:** 1252**Subject No:** 12521011**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 35	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Alkaline Phosphatase_PX35	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 65	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 50 <i>High</i> 250 <i>Unit</i> U/L	Initial Entry

5.e

Date	Location	User	Value	Reason
Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Bilirubin_PX 21 Result:: 0.5 Not Done::	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021

Form Version: 21-Aug-2020 02:49

Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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

			Lab Normal Range:	<i>Low</i> 0.1	
				<i>High</i> 1.2	
				<i>Unit</i> mg/dL	

5.e Sponsor ID:

Date	Location	User	Value	Reason
Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 21	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Bilirubin_PX21	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 0.5	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <i>Low</i> 0.1 <i>High</i> 1.2 <i>Unit</i> mg/dL	Initial Entry

5.f

Date	Location	User	Value	Reason
Jan-11-2021 15:18:11	ACV0PFEINFP6000	auto calc	<u>Data Entry:</u>	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

Form Version: 21-Aug-2020 02:49

Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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

(UTC-05:00) Eastern Time
(US & Canada)

(autocalc)

Sponsor-Defined Identifier: 47

Test:: Blood Urea Nitrogen_PX47

Result:: 16

Not Done::

Lab Normal Range: Low
9

High
20

Unit
mg/dL

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

5.f Sponsor ID:

Date	Location	User	Value	Reason
Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 47	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Blood Urea Nitrogen_PX47	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 16	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 9 <i>High</i> 20 <i>Unit</i> mg/dL	Initial Entry

5.g

Date	Location	User	Value	Reason
Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 48 Test:: Creatinine_PX 48 Result:: 0.96 Not Done::	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

Form Version: 21-Aug-2020 02:49

Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - 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

			Lab Normal Range: <i>Low</i> 0.66 <i>High</i> 1.25 <i>Unit</i> mg/dL
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5.g Sponsor ID:

Date	Location	User	Value	Reason
Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 48	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Creatinine_PX48	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.96	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Jan-11-2021 15:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.66 <i>High</i> 1.25 <i>Unit</i> mg/dL	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

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: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Jan-11-2021 15:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit
Trail History**Form Version:** 21-Aug-2020 02:51**Form Status:** Data Complete, Frozen, Verified**Site No:** 1252**Site Name:** (1252) Waterway Primary Care LLC DBA Tabor City Family
Medicine**Subject No:** 12521011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-11-2021 15:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HEMATOLOGY	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Jan-11-2021 15:44:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: McLeod Loris Hospital 3612 Mitchell S treet Loris SC 29569	Initial Entry
Jan-11-2021 15:43:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jan-11-2021 15:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: McLeod Loris Hospital 3612 Mitchell S treet Loris SC 29569	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-11-2021 15:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Jan-11-2021 15:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-11-2021 15:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Hemoglobin_P X1 Result:: 12.0 Not Done::	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

			Lab Normal Range: <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-11-2021 15:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 1	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Jan-11-2021 15:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Hemoglobin_PX1	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Jan-11-2021 15:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 12.0	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Jan-11-2021 15:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <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-11-2021 15:28:01	ACV0PFEINFP6000	auto calc	<u>Data Entry:</u>	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

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Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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Subject Initials: ---

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(UTC-05:00) Eastern Time (US & Canada)	(autocalc)	Sponsor-Defined Identifier: 2	
		Test:: Hematocrit_P X2	
		Result:: 36.2	
		Not Done::	
		Lab Normal Range: <i>Low</i> 42.0	
		<i>High</i> 52.0	
		<i>Unit</i> %	

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

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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: 12521011

Subject Initials: ---

Generated By: (b) (4)

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5.b Sponsor ID:

Date	Location	User	Value	Reason
Jan-11-2021 15:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Jan-11-2021 15:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hematocrit_PX2	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Jan-11-2021 15:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.2	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Jan-11-2021 15:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 42.0 <i>High</i> 52.0 <i>Unit</i> %	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-11-2021 15:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 3 Test:: Erythrocytes_P X3 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

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Header Text: c4591001

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Form Status: Data Complete, Frozen, Verified

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sponsor ID:

Date	Location	User	Value	Reason
Jan-11-2021 15:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Jan-11-2021 15:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Erythrocytes_PX3	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Jan-11-2021 15:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-11-2021 15:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Platelets_P X5 Result:: 214 Not Done:: Lab Normal Range: Low 150 High 450 Unit /uL	Initial Entry
Jan 11 2021 15 30 14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Platelets_P X5 Result:: Not Done::	New Information

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Header Text: c4591001

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Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

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			Lab Normal Range: <i>Low</i> 150 <i>High</i> 450 <i>Unit</i> /uL	
Jan-11-2021 15:29:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Platelets_P X5 Result:: Not Done:: Lab Normal Range: <i>Low</i> 150 <i>High</i> 450	Transcription Error
Jan-11-2021 15:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Platelets_P X5 Result:: 214 Not Done:: Lab Normal Range: <i>Low</i> 150 <i>High</i> 450	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sponsor ID:

Date	Location	User	Value	Reason
Jan-11-2021 15:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 5	Initial Entry
Jan-11-2021 15:29:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Transcription Error
Jan-11-2021 15:28:01 (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
Jan-11-2021 15:28:01 (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-11-2021 15:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 214	Initial Entry
Jan-11-2021 15:29:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-11-2021 15:29:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Transcription Error
Jan-11-2021 15:28:01 (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-11-2021 15:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 214	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
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Jan-11-2021 15:30:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 150 <i>High</i> 450 <i>Unit</i> /uL	New Information
Jan-11-2021 15:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 150 <i>High</i> 450	Initial Entry

5.e

Date	Location	User	Value	Reason
Jan-11-2021 15:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Leukocytes_P X7 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry
Jan-11-2021 15:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Leukocytes_P X7 Result:: Not Done:: Lab Normal Range:	Initial Entry

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Header Text: c4591001

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

5.e Sponsor ID:

Date	Location	User	Value	Reason
Jan-11-2021 15:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Jan-11-2021 15:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Leukocytes_PX7	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Jan-11-2021 15:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

5.f

Date	Location	User	Value	Reason
Jan-11-2021 15:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 608 Test:: Neutrophils_P X608 Result:: 13.9 Not Done:: Lab Normal Range: Low 1.9 High 7.6 Unit 10^9/L	Initial Entry
Jan 11 2021 15 28 01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 608 Test:: Neutrophils_P X608 Result:: Not Done::	Initial Entry

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Header Text: c4591001

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			Lab Normal Range:	
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5.f Sponsor ID:

Date	Location	User	Value	Reason
Jan-11-2021 15:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 608	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Jan-11-2021 15:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Neutrophils_PX608	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Jan-11-2021 15:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 13.9	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Jan-11-2021 15:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 1.9 <i>High</i> 7.6 <i>Unit</i> 10 ⁹ /L	Initial Entry

5.g

Date	Location	User	Value	Reason
Jan-11-2021 15:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 609 Test:: Eosinophils_P X609 Result:: 0.0 Not Done::	Initial Entry

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Header Text: c4591001

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Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

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

Subject Initials: ---

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			Lab Normal Range: <i>Low</i> 0.00 <i>High</i> 0.50 <i>Unit</i> 10 ⁹ /L	
Jan-11-2021 15:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Eosinophils_P X609 Result:: Not Done:: Lab Normal Range:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

5.g Sponsor ID:

Date	Location	User	Value	Reason
Jan-11-2021 15:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 609	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Jan-11-2021 15:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Eosinophils_PX609	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Jan-11-2021 15:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.0	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Jan-11-2021 15:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.00 <i>High</i> 0.50 <i>Unit</i> 10^9/L	Initial Entry

5.h

Date	Location	User	Value	Reason
Jan-11-2021 15:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Monocytes_PX 612 Result:: 0.9 Not Done::	Initial Entry

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			Lab Normal Range: <i>Low</i> 0.2 <i>High</i> 1.5 <i>Unit</i> 10^9/L	
Jan-11-2021 15:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Monocytes_PX 612 Result:: Not Done:: Lab Normal Range:	Initial Entry

5.h Sponsor ID:

Date	Location	User	Value	Reason
Jan-11-2021 15:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 612	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Jan-11-2021 15:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Monocytes_PX612	Initial Entry

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Subject Initials: ---

Generated By: (b) (4)

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5.h Result:

Date	Location	User	Value	Reason
Jan-11-2021 15:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.9	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Jan-11-2021 15:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.2 <i>High</i> 1.5 <i>Unit</i> 10^9/L	Initial Entry

5.i

Date	Location	User	Value	Reason
Jan-11-2021 15:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Basophils_PX 610 Result:: 0.0 Not Done:: Lab Normal Range: <i>Low</i> 0.0 <i>High</i> 0.2 <i>Unit</i> 10^9/L	Initial Entry
Jan-11-2021 15:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Basophils_PX 610 Result:: Not Done::	Initial Entry

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Subject Initials: ---

Generated By: (b) (4)

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

			Lab Normal Range:	
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5.i Sponsor ID:

Date	Location	User	Value	Reason
Jan-11-2021 15:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 610	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Jan-11-2021 15:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Basophils_PX610	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Jan-11-2021 15:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.0	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Jan-11-2021 15:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.0 <i>High</i> 0.2 <i>Unit</i> 10^9/L	Initial Entry

5.j

Date	Location	User	Value	Reason
Jan-11-2021 15:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 611 Test:: Lymphocytes_P X611 Result:: 1.1 Not Done::	Initial Entry

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Header Text: c4591001

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Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

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Form Status: Data Complete, Frozen, Verified

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Subject Initials: ---

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			Lab Normal Range: <i>Low</i> 1.1 <i>High</i> 4.8 <i>Unit</i> 10^9/L	
Jan-11-2021 15:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Lymphocytes_P X611 Result:: Not Done:: Lab Normal Range:	Initial Entry

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Subject Initials: ---

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5.j Sponsor ID:

Date	Location	User	Value	Reason
Jan-11-2021 15:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 611	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Jan-11-2021 15:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Lymphocytes_PX611	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Jan-11-2021 15:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1.1	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Jan-11-2021 15:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 1.1 <i>High</i> 4.8 <i>Unit</i> 10^9/L	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021

Form: VITAL SIGNS - COVID - Audit Trail

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: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Jan-11-2021 15:51:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

Form: VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date:

Date	Location	User	Value	Reason
Jan-11-2021 15:51:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-11-2021 15:54:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: 14 0 Diastolic:: 62 Respiratory Rate in respirations/ minute: 20 Heart Rate in beats/minute: 58	New Information
Jan-11-2021 15:53:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: 14 0 Diastolic:: 51 Respiratory Rate in respirations/ minute: 20 Heart Rate in beats/minute: 58	New Information
Jan-11-2021 15:51:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: 14 4 Diastolic:: 51 Respiratory Rate in respirations/ minute: 20 Heart Rate in beats/minute: 58	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-11-2021 15:51:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Systolic:

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

Form: VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Jan-11-2021 15:53:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-11-2021 15:53:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 140	New Information
Jan-11-2021 15:51:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 144 is outside of Normal Range 90 - 140.
Jan-11-2021 15:51:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 144	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Jan-11-2021 15:54:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-11-2021 15:54:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 62	New Information
Jan-11-2021 15:51:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Diastolic BP 51 is outside of Normal Range 60 - 90.
Jan-11-2021 15:51:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 51	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Jan-11-2021 15:51:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 20	Initial Entry

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Jan-11-2021 15:51:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 58	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR - 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: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Jan-11-2021 15:55:39 (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 Jan/11/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date:

Date	Location	User	Value	Reason
Jan-11-2021 15:55:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-11-2021 15:55:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Oxygen Saturation: 47.0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Jan-11-2021 15:55:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Jan-11-2021 15:55:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 47.0	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021

Form: OXYGENATION PARAMETERS - Audit Trail

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: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Jan-13-2021 13:54:08 (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 Jan/11/2021

Form: OXYGENATION PARAMETERS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

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
Jan-13-2021 13:54:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021 17:40	Initial Entry
Jan-13-2021 13:16:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	New Information
Jan-11-2021 15:56:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Arterial Blood Gases PaO2 (mmHg):

Date	Location	User	Value	Reason
Jan-13-2021 13:54:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 83	Initial Entry
Jan-13-2021 13:16:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	New Information
Jan-11-2021 15:58:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. FiO2 (Fraction of Inhaled Oxygen):

Date	Location	User	Value	Reason
Jan-13-2021 13:54:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.30	Initial Entry
Jan-13-2021 13:16:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	New Information
Jan-11-2021 15:58:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Audit Trail

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: 12521011

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-09-2021 08:15:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/11/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

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

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4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Feb-10-2021 05:47:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-09-2021 08:15:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Feb-09-2021 04:34:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 2: Opened	Please consider deleting the logline if there is no data to be reported for this line. To delete the log entries, go in the Log Summary page and select the 'Delete' option at the bottom left of the screen and click 'Apply'.
Feb-05-2021 04:30:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-04-2021 08:08:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-04-2021 02:17:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	Please consider deleting the logline if there is no data to be reported for this line. To delete the log entries, go in the Log Summary page and select the 'Delete' option at the bottom left of the screen and click 'Apply'.
Jan-11-2021 16:00:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

5. Start Date:				
Date	Location	User	Value	Reason
Jan-11-2021 16:00:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?				
Date	Location	User	Value	Reason
Jan-11-2021 16:00:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Jan/11/2021

Form: IMAGING - Audit Trail

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: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Jan-11-2021 16:08:16 (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
Jan/11/2021

Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

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
Jan-11-2021 16:08:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Jan-11-2021 16:08:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHEST	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Jan-11-2021 16:08:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: X-RAY	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Jan-11-2021 16:08:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ABNORMAL <i>If abnormal, specify findings:</i> Coarsened interstitium with nodular r ight lower lung density	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Feb/10/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-10-2021 11:08:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/10/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Feb-10-2021 11:08:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_A1	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled Visit
on Feb/10/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1252**Subject No:** 12521011**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[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-10-2021 11:08:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-10-2021 11:08:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-10-2021 11:09:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-10-2021 11:08:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-10-2021 11:08:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/10/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-10-2021 11:09:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPYY5K	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-10-2021 11:09:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPYY5K	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Feb/10/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

5.b

Date	Location	User	Value	Reason
Feb-10-2021 11:09:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNWG75	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-10-2021 11:09:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNWG75	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-10-2021 11:10:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BNWG74	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-10-2021 11:10:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BNWG74	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-12-2020 13:25:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/12/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-12-2020 13:25:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-12-2020 13:25:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae30e7\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: 12521011

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-08-2021 10:30:27 (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: 12521011

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-19-2021 15:50:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Undeleted	New Information
Jan-19-2021 15:02:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	New Information
Jan-19-2021 15:01:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Undeleted	Transcription Error
Jan-19-2021 15:00:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Jan-19-2021 15:00:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Undeleted	Transcription Error
Jan-15-2021 09:44:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Jan-15-2021 09:29:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae30e7\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: 12521011

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-19-2021 14:55:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae30e7\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

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Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Feb-26-2021 13:27:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Transcription Error
Jan-19-2021 15:05:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1252

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Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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Date	Location	User	Value	Reason
Jan-19-2021 15:11:57 (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: 12521011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

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Date	Location	User	Value	Reason
Jan-19-2021 15:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

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Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

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Date	Location	User	Value	Reason
Jan-19-2021 15:58:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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Header Text: c4591001

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Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

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Date	Location	User	Value	Reason
Jan-21-2021 09:09:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

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Date	Location	User	Value	Reason
Jan-21-2021 09:11:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

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1. Category:

Date	Location	User	Value	Reason
Jan-08-2021 10:30:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-08-2021 10:30:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-19-2021 09:37:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Closed	Thanks
Feb-09-2021 08:33:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Follow up has been provided and submitted by fax in on 03Feb2021, with the levels that were provided for this event.
Feb-08-2021 14:26:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Reissued:Opened	Very much appreciate you response. Pls provide this information in a FU form so this is added to the safety report. Thank you.
Feb-03-2021 14:56:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Hyperkalemia level was 5.4 mmol/L on 01/06/2021 Blood oxygen level (O2 saturation) was 47.0 % on 01/06/2021
Feb-03-2021 13:21:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Reissued:Opened	Appreciate the update. Pls clarify SAE of Hypokalemia, the potassium levels are missing in report. Additionally, pls

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Header Text: c4591001

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Subject No: 12521011

Generated By: (b) (4)

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				provide value of blood oxygen. Per narrative "Blood oxygen levels were low." Thanks
Jan-25-2021 12:37:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Follow up report with results is submitted
Jan-24-2021 11:00:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Reissued:Opened	Please clarify, if "Subject had a high elevated troponin.", associated with CAD, do you have additional workup on acute Myocardial Infarction or for events of sepsis, pneumonia? Please provide Lab results, imaging and treatment in a FU report. Thanks
Jan-19-2021 15:14:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Original value is correct
Jan-19-2021 11:59:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Reissued:Opened	Thank you your response, was there additional work up or other diagnosis done?
Jan-13-2021 09:31:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Troponin level 0.035 ng/ml
Jan-13-2021 08:29:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Opened	CLINICAL_ Per report submitted to safety, "Subject had a high elevated troponin." Please provide the value cTnT and if additional work up or other diagnosis was made. Thank you.
Jan-12-2021 16:25:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Jan-11-2021 16:14:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	A Potential Covid 19 visit has been completed 11Jan2021. Subject was able to collect a sample from

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				his Self Nasal Swab Home kit and dropped it off at the site today 11Jan2021. The sample will be picked up by Marken on 12Jan2021
Jan-11-2021 11:36:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Subject experienced SHORTNESS OF BREATH and possible PNEUMONIA that should have please triggered a COVID-19 Visit irrespective of perceived etiology or clinical significance and captured only on the CRF SOD form and a swab collected ASAP
Jan-08-2021 10:30:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> COPD exacerbation	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-08-2021 10:30:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Jan/6/2021 16:53	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-15-2021 09:35:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date Time: Jan/10/2021 10:10	New Information
Jan-08-2021 10:30:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-08-2021 10:30:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 3	Initial Entry

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Generated By: (b) (4)

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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Jan-19-2021 14:51:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event YES	Transcription Error
Jan-11-2021 02:28:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally
Jan-08-2021 10:30:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE COPD exacerbation: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-08-2021 10:30:27	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

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(UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? 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
Jan-08-2021 10:30:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-08-2021 10:30:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: Increased shortness of breath	Initial Entry

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Form Status: Data Complete, Verified

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

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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-08-2021 10:30:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-08-2021 10:30:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-08-2021 10:30:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-15-2021 15:50:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Closed	Auto closed by Validation Check: VC_AE001_35
Jan-15-2021 09:42:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Original value is correct
Jan-14-2021 23:40:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-14-2021 20:41:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Opened	DMW6841661;Response to "What was the outcome of this adverse event?" is 'Recovered/Resolved' or 'Recovered/Resolved with Sequelae' but End Date/Time is missing.

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Canada)				Please review and update as appropriate.
Jan-13-2021 08:12:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Ans wered	New Information
Jan-13-2021 08:12:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : RECO VERE D/RE SOLV ED	New Information
Jan-13-2021 04:29:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Op ened	SAE RECON:AER#2021015418 ,outcome was updated to RECOVERED/RESOLVED in Safety DB while reported as Not RECOVERING/RESOLVING in AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Jan-12-2021 21:39:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Response satisfies query
Jan-11-2021 12:46:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry : RECO VERI NG/R ESOL VING	Transcription Error
Jan-11-2021 11:42:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	New Information
Jan-11-2021 11:42:18	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry	New Information

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(UTC-05:00) Eastern Time (US & Canada)			RECOVERED	
Jan-11-2021 06:42:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2021015418,outcome was reported as Recovering/Resolving to Safety DB however, recorded as NOT RECOVERED/NOT RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Jan-08-2021 10:30:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-08-2021 10:30:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Jan-11-2021 06:40:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021015418	Initial Entry

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1252**Subject No:** 12521011**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Not Complete**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. Category:**

Date	Location	User	Value	Reason
Jan-19-2021 15:54:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry
Jan-19-2021 15:51:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry
Jan-15-2021 09:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jan-15-2021 09:38:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Jan-15-2021 09:29:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-19-2021 15:54:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry
Jan-19-2021 15:51:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry
Jan-15-2021 09:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Jan-15-2021 09:38:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Jan-15-2021 09:29:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
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Header Text: c4591001

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Feb-16-2021 09:02:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Elevated Troponin	Transcription Error
Jan-19-2021 15:54:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CAD with elevated Troponin	Initial Entry
Jan-19-2021 15:51:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-15-2021 09:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-15-2021 09:38:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jan-15-2021 09:29:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COPD exacerbation	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-19-2021 15:54:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021 16:53	Initial Entry
Jan-19-2021 15:51:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-15-2021 09:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-15-2021 09:39:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jan-15-2021 09:29:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021 16:53	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-19-2021 15:54:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time:	Initial Entry

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			Jan/10/2021 10:10	
Jan-19-2021 15:51:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-15-2021 09:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-15-2021 09:39:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jan-15-2021 09:29:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/10/2021 10:10	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-23-2021 14:15:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Transcription Error
Jan-19-2021 15:54:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry
Jan-19-2021 15:51:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-15-2021 09:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-15-2021 09:40:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jan-15-2021 09:29:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	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

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medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-24-2021 03:55:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query
Feb-23-2021 14:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	For AE Elevated Troponin: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Feb-23-2021 14:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Transcription Error
Jan-20-2021 07:18:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Deleted	Query can be addressed internally
Jan-19-2021 15:54:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE CAD with elevated Troponin: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-19-2021 15:54:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolonged hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening?	Initial Entry

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			<p>YES</p> <p>Other medically important serious event</p> <p>YES</p>	
Jan-19-2021 15:51:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-15-2021 09:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-15-2021 09:40:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jan-15-2021 09:38:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-15-2021 09:31:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE COPD exacerbation: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-15-2021 09:31:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening?	New Information

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			NO Other medically important serious event NO	
Jan-15-2021 09:29:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Jan-19-2021 15:54:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Jan-19-2021 15:51:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-15-2021 09:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-15-2021 09:40:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jan-15-2021 09:29:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-19-2021 15:54:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Heart problem	Initial Entry
Jan-19-2021 15:51:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-15-2021 09:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-15-2021 09:40:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jan-15-2021 09:34:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Increased shortness of breath	New Information
Jan-15-2021 09:29:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> COPD exacerbation	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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Jan-19-2021 15:54:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry
Jan-19-2021 15:51:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-15-2021 09:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-15-2021 09:41:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jan-15-2021 09:29:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

II. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-23-2021 14:34:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error
Jan-19-2021 15:54:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
Jan-19-2021 15:51:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-15-2021 09:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-15-2021 09:41:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jan-15-2021 09:29:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-19-2021 15:54:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

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Jan-19-2021 15:51:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-15-2021 09:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-15-2021 09:41:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jan-15-2021 09:29:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-19-2021 15:54:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry
Jan-19-2021 15:51:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-15-2021 09:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Jan-15-2021 09:41:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jan-15-2021 09:29:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-19-2021 15:54:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Jan-19-2021 15:51:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-15-2021 09:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Jan-15-2021 09:41:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error
Jan-15-2021 09:29:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Feb-24-2021 03:55:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	event downgraded
Jan-20-2021 23:09:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021015418	Initial Entry
Jan-19-2021 15:51:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Initial Entry
Jan-15-2021 09:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Jan-19-2021 14:55:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-19-2021 14:55:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-19-2021 14:55:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sepsis	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-19-2021 14:55:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021 16:53	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-19-2021 14:55:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/10/2021 10:10	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-23-2021 14:18:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Transcription Error
Jan-19-2021 14:55:51	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

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(UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	3
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-24-2021 03:55:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Feb-23-2021 14:18:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE Sepsis: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Feb-23-2021 14:18:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error
Jan-20-2021 07:18:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally
Jan-19-2021 14:55:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Sepsis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-19-2021 14:55:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with c ongenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolo ng hospitalization? YES	Initial Entry

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			<p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>YES</p> <p>Other medically important serious event</p> <p>YES</p>	
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8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Jan-19-2021 14:55:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-19-2021 14:57:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Probably due to Pneumonia	New Information
Jan-19-2021 14:55:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-19-2021 14:55:51 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

090177e196ae30e7\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: 12521011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

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)		
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-19-2021 14:55:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-19-2021 14:55:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-19-2021 14:55:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-19-2021 14:55:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Feb-24-2021 03:55:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	event downgraded
Jan-20-2021 23:08:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021015418	Initial Entry

090177e196ae30e7\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: 12521011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Not Verified

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

Subject Initials: ---

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

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

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1. Category:

Date	Location	User	Value	Reason
Jan-19-2021 15:05:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-19-2021 15:05:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-02-2021 15:22:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Feb-26-2021 09:12:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	inactivate log line
Feb-25-2021 16:45:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Per Prot Sect 8.3.7., COVID-19 related COVID-19 PNEUMONIA does not qualify as AE and please should be documented only on the COVID-19 CRF ILLNESS DETAILS form ONLY as PNEUMONIA and should not be captured on the AE CRF page.
Jan-19-2021 15:05:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Pneumonia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
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090177e196ae30e7\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: 12521011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Not 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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Jan-19-2021 15:05:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021 16:53	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-19-2021 15:05:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/10/2021 10:10	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-23-2021 14:22:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Transcription Error
Jan-19-2021 15:05:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-24-2021 03:56:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Feb-23-2021 14:22:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE Pneumonia: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Feb-23-2021 14:22:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error
Jan-20-2021 07:18:13 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (6)	Query 1: Deleted	Query can be addressed internally

090177e196ae30e7\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: 12521011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Not Verified

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

Subject Initials: ---

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(US & Canada)		(b) (4)		
Jan-19-2021 15:05:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Pneumonia: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-19-2021 15:05:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event YES	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-19-2021 15:05:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Not Verified

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Jan-25-2021 07:23:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-22-2021 08:25:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Infection	Transcription Error
Jan-22-2021 08:24:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Transcription error
Jan-22-2021 06:45:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	Per Prot Sect 8.3.7., COVID 19 related Symptoms does not qualify as AE and please should be documented only on the COVID 19 CRF ILLNESS DETAILS form ONLY and should not be captured on the AE CRF page. Kindly review and update as necessary else clarify (b) (4)
Jan-19-2021 15:05:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to:	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Not Verified

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

Subject Initials: ---

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

			e to:	
			OTHER	
			<i>If Other, specify:</i>	
			Pneumonia-Covid-19 negative	

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-19-2021 15:05:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-19-2021 15:05:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-19-2021 15:05:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-19-2021 15:05:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-19-2021 15:05:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

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Subject No: 12521011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted, Not Verified

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Feb-24-2021 03:56:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	event downgraded
Jan-20-2021 22:49:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2021015418	Initial Entry

090177e196ae30e7\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:** 12521011**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - 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](#)**1. Category:**

Date	Location	User	Value	Reason
Jan-19-2021 15:11:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-19-2021 15:11:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

3. Adverse Event:*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Jan-21-2021 14:28:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-21-2021 09:05:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Jan-21-2021 06:15:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD CLINQUERY: SAE information (case 2021015418) reports low platelets and lymphocytes, as well as leucocytosis. Please also record these as adverse events in the CRF.
Jan-19-2021 15:11:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Anemia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-19-2021 15:11:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021 16:53	Initial Entry

5. Is the adverse event still ongoing?

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Subject No: 12521011

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Jan-19-2021 15:11:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/10/2021 10:10	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-19-2021 15:11:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-24-2021 03:56:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Feb-23-2021 14:23:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE Anemia: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Feb-23-2021 14:23:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error
Jan-25-2021 03:39:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-21-2021 08:56:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death?	Transcription Error

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Subject No: 12521011

Generated By: (b) (4)

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Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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			<p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>YES</p> <p>Other medically important serious event</p> <p>YES</p>	
Jan-21-2021 08:55:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Anemia: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-21-2021 08:55:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p>Data Entry:</p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p>	Transcription Error

Header Text: c4591001

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Subject No: 12521011

Generated By: (b) (4)

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			YES Other medically important serious event NO	
Jan-19-2021 15:11:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Jan-19-2021 15:11:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-19-2021 15:11:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: Probably due to anemia of chronic disease and without any symptoms of bleeding.	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-19-2021 15:11:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-23-2021 14:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

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Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Jan-19-2021 15:11:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-19-2021 15:11:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-19-2021 15:11:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-19-2021 15:11:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Feb-24-2021 03:56:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Event Downgraded in Inform
Jan-25-2021 03:39:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021015418	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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I. Category:

Date	Location	User	Value	Reason
Jan-19-2021 15:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-19-2021 15:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-22-2021 11:43:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	GPD CLINQUERY: Will follow-up with the Safety group.
Jan-21-2021 15:50:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hyperkalemia	New Information
Jan-21-2021 15:48:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Jan-21-2021 15:48:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hyperkalemia SAE case 2021015418	New Information
Jan-21-2021 14:37:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	GPD CLINQUERY: As hyperkalemia is related to the SAE case, please update the information reported in the SAE.
Jan-21-2021 09:00:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Hyperkalemia is related to SAE case 2021015418
Jan-21-2021 06:19:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD CLINQUERY: Please confirm if hyperkalemia is related to SAE case 2021015418 and

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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

				update information provided in SAE report accordingly.
Jan-19-2021 15:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hyperkalemia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-19-2021 15:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021 16:53	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-19-2021 15:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/10/2021 10:10	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-19-2021 15:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-24-2021 03:57:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Feb-23-2021 14:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE Hyperkalemia : Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1252

Subject No: 12521011

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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Feb-23-2021 14:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error
Jan-25-2021 03:43:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-21-2021 15:50:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Hyperkalemia : Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-21-2021 15:48:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Hyperkalemia SAE case 2021015418: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-21-2021 09:01:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Hyperkalemia: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-21-2021 09:01:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening?	Transcription Error

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Subject No: 12521011

Generated By: (b) (4)

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			YES Other medically important serious event YES	
Jan-19-2021 15:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Jan-19-2021 15:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-21-2021 14:55:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-21-2021 14:24:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Potassium level high in blood	Transcription Error
Jan-21-2021 14:13:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-21-2021 14:13:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Potassium level high	Transcription Error

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Jan-21-2021 11:25:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: pls advise on biological basis for causality. Thanks
Jan-19-2021 15:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), t his event is due to: OTHER <i>If Other, specify:</i> Hypoxia-resolved	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-19-2021 15:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-23-2021 14:33:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error
Jan-19-2021 15:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-19-2021 15:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-19-2021 15:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
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Jan-19-2021 15:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
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15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Feb-24-2021 03:57:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Event Downgraded in Inform
Jan-25-2021 04:48:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-25-2021 03:43:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021015418	Initial Entry
Jan-22-2021 12:16:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SAE case number 2021015418
Jan-22-2021 11:28:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	GPD CLINQUERY: Thank you for confirming. Please add the SAE number in the CRF.
Jan-21-2021 15:49:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	SAE case 2021015418
Jan-21-2021 14:31:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD CLINQUERY: As event is related to SAE, please add associated SAE case number.

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1252**Subject No:** 12521011**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Not Complete**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. Category:**

Date	Location	User	Value	Reason
Jan-19-2021 15:58:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-19-2021 15:58:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

3. Adverse Event:*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Jan-19-2021 15:58:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Chronic Hypoxic respiratory failure	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-19-2021 15:58:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021 16:53	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-19-2021 15:58:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/10/2021 10:10	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-23-2021 14:25:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Transcription Error
Jan-19-2021 15:58:00	ACV0PFEINFP6000	(b) (6)	Data Entry:	Initial Entry

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(UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	3
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-24-2021 03:57:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Feb-23-2021 14:24:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE Chronic Hypoxic respiratory failure: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Feb-23-2021 14:24:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error
Jan-20-2021 07:18:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	Query can be addressed internally
Jan-19-2021 15:58:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Chronic Hypoxic respiratory failure: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-19-2021 15:58:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization?	Initial Entry

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Subject No: 12521011

Generated By: (b) (4)

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			<p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>YES</p> <p>Other medically important serious event</p> <p>YES</p>	
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8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Jan-19-2021 15:58:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-19-2021 15:58:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Not enough of oxygen in the blood	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-19-2021 15:58:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

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Form Version: 22-Apr-2020 21:02

Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

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Form Status: Data Complete, Frozen, Not Complete

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
Feb-23-2021 14:32:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Transcription Error
Jan-19-2021 15:58:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-19-2021 15:58:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-19-2021 15:58:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-19-2021 15:58:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Feb-24-2021 03:57:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Event Downgraded in Inform
Jan-20-2021 22:48:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2021015418	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

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Subject No: 12521011

Generated By: (b) (4)

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1. Category:

Date	Location	User	Value	Reason
Jan-21-2021 09:09:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-21-2021 09:09:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-21-2021 09:09:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Low platelets	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-21-2021 09:09:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021 16:53	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-21-2021 09:09:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/10/2021 10:10	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-21-2021 09:09:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

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If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-24-2021 03:57:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Feb-23-2021 14:26:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE Low platelets: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Feb-23-2021 14:26:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error
Jan-25-2021 03:44:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-21-2021 09:09:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Low platelets: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-21-2021 09:09:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity?	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

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

Subject Initials: ---

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			NO	
			Is this serious event life threatening?	
			YES	
			Other medically important serious event	
			YES	

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-21-2021 09:09:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-21-2021 09:09:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Low number of platelets in blood	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-21-2021 09:09:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-23-2021 14:30:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error
Jan-21-2021 09:09:02 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (6)	Data Entry: YES	Initial Entry

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Header Text: c4591001

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Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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(US & Canada)		(b) (4)	
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-21-2021 09:09:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-21-2021 09:09:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-21-2021 09:09:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Feb-24-2021 03:57:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Event Downgraded in Inform
Jan-25-2021 03:44:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2021015418	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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I. Category:

Date	Location	User	Value	Reason
Jan-21-2021 09:11:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-21-2021 09:11:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-10-2021 15:13:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-10-2021 10:42:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Feb-10-2021 10:42:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Low Lymphocytes	Transcription Error
Feb-09-2021 12:44:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON: AE of "LOW LYMPHOCYTES" has been reported in SDB however "Lymphocytes" is reported in CRF. Please review and update accordingly. If safety update is required, submit a follow-up SAE Form.
Jan-28-2021 12:21:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-27-2021 12:16:31 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Low Lymphocytes

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Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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(US & Canada)				
Jan-27-2021 11:37:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	GPD CLINQUERY: Please update the actual AE term on the CRF page to 'low lymphocytes'.
Jan-26-2021 08:44:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Low Lymphocytes
Jan-26-2021 06:59:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	GPD CLINQUERY: Thank you. Please update the AE term to indicate low lymphocytes.
Jan-25-2021 12:35:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Labs showed on 06Jan2021 that Lymphocytes was low at 7.0 mcl
Jan-25-2021 11:57:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD CLINQUERY: Please clarify 'lymphocytes' e.g. increased lymphocytes vs decreased lymphocytes.
Jan-21-2021 09:11:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Lymphocytes	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-21-2021 09:11:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/6/2021 16:53	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-21-2021 09:11:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Jan/10/2021 10:10	Initial Entry

6. Toxicity Grade:

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Header Text: c4591001

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Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - 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

Date	Location	User	Value	Reason
Jan-21-2021 09:11:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-24-2021 03:58:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Feb-23-2021 14:27:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	For AE Low Lymphocytes: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Feb-23-2021 14:27:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Transcription Error
Jan-25-2021 03:44:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-21-2021 09:11:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Lymphocytes: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-21-2021 09:11:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO	Initial Entry

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			<p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>YES</p> <p>Other medically important serious event</p> <p>YES</p>	
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8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Jan-21-2021 09:11:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-21-2021 09:11:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: Infection	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-21-2021 09:11:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

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Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Subject Initials: ---

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Date	Location	User	Value	Reason
Feb-23-2021 14:29:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Transcription Error
Jan-21-2021 09:11:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-21-2021 09:11:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-21-2021 09:11:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-21-2021 09:11:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Feb-24-2021 03:58:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Event Downgraded in Inform
Jan-25-2021 03:44:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2021015418	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1252

Subject No: 12521011

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
Jan-08-2021 10:30:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Medication Error (Type of Medication Error):

Date	Location	User	Value	Reason
Jan-08-2021 10:30:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Start Date:

Date	Location	User	Value	Reason
Jan-08-2021 10:30:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Is the medication error still ongoing?

Date	Location	User	Value	Reason
Jan-08-2021 10:30:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-08-2021 10:30:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-08-2021 10:30:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

7. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1252

Subject No: 12521011

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

Jan-08-2021 10:30:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
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8. Did the Medication Error cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-08-2021 10:30:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

9. Was this medication error associated with any adverse events?

Date	Location	User	Value	Reason
Jan-08-2021 10:30:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

10. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Jan-08-2021 10:30:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	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: 12521011

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 10:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-08-2021 10:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jan-08-2021 10:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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 10:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Jan-08-2021 10:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Site No: 1252

Subject No: 12521011

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED - 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. What is the medication identifier?

Date	Location	User	Value	Reason
Jan-08-2021 10:31:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-08-2021 10:31:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jan-08-2021 10:31:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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 10:31:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Jan-08-2021 10:31:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Jan-08-2021 10:31:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

7. Dose Frequency:

Date	Location	User	Value	Reason
Jan-08-2021 10:31:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Jan-08-2021 10:31:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Jan-08-2021 10:31:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Jan-08-2021 10:31:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1252

Subject No: 12521011

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
Jan-08-2021 10:32:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. What is the treatment Identifier?

Date	Location	User	Value	Reason
Jan-08-2021 10:32:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Jan-08-2021 10:32:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Jan-08-2021 10:32:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Jan-08-2021 10:32:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Jan-08-2021 10:32:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Form Version: 22-Apr-2020 21:03

Site No: 1252

Subject No: 12521011

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
Jan-08-2021 10:32:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Date of Transfusion:

Date	Location	User	Value	Reason
Jan-08-2021 10:32:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

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
Feb-16-2021 12:16:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/12/2021	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1252

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

Subject No: 12521011

Subject Initials: ---

Generated By: (b) (4)

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

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

Date	Location	User	Value	Reason
Feb-24-2021 08:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2	Transcription Error
Feb-16-2021 12:16:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible	Initial Entry

090177e196ae30e7\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: 12521011

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
Feb-15-2021 14:45:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Jan/12/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-24-2021 17:33:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_DS001_35
Feb-24-2021 08:53:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-22-2021 20:16:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7350856;Primary Reason for Unblinding is "ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION", but "Participant is willing to return for Vaccination 3" is not selected in the Further Vaccination Confirmation CRF. Please review and update as appropriate.
Feb-15-2021 14:45:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae30e7\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: 12521011

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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1. Withdrawal of Consent Date :

Date	Location	User	Value	Reason
Feb-15-2021 14:45:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1252

Subject No: 12521011

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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1. Date of Collection / Notification of Death:

Date	Location	User	Value	Reason
Feb-15-2021 14:46:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae30e7\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: 12521011

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
Oct-12-2020 13:25:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-25-2020 17:21:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-21-2020 06:26:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-12-2020 13:25:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/12/2020	Initial Entry
Aug-25-2020 17:21:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/17/2020	Initial Entry
Aug-21-2020 06:26:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/17/2020	Initial Entry

090177e196ae30e7\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: 12521011

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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I. Casebook Signature

Date	Location	User	Value	Reason
Oct-21-2020 17:10:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae30e7\Final\Final On: 01-Apr-2021 04:19 (GMT)