

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** COHORT\_SELECTION

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[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	30 JUN 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** MAIN INFORMED CONSENT

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/21/2020
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**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** DEMOGRAPHY

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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**Demography**

1.	Subject ID	[12261338]
2.	Birth Date:	(b) (6)/1989
3.	Sex:	FEMALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	ASIAN
6.	Racial Designation:	OTHER

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** DATE OF VISIT

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Aug/21/2020
2.	Erroneous Visit	

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclusion criteria (NO).

**Inclusion Criteria**

1.a	Inclusion Number:	1
	Criterion Description:	Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN01A00

1.b	Inclusion Number:	2
	Criterion Description:	Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN02A00

1.c	Inclusion Number:	3
	Criterion Description:	Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN03A00

1.d	Inclusion Number:	4
	Criterion Description:	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN04A00

**Exclusion Criteria**

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**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

2.a	Exclusion Number:	1
	Criterion Description:	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX01A00
2.b	Exclusion Number:	2
	Criterion Description:	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX02A00
2.c	Exclusion Number:	3
	Criterion Description:	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX03A00
2.d	Exclusion Number:	4
	Criterion Description:	Receipt of medications intended to prevent COVID-19
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX04A00
2.e	Exclusion Number:	8
	Criterion Description:	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX08A00

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**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

2 f	Exclusion Number:	10
	Criterion Description:	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX10A00
2.g	Exclusion Number:	11
	Criterion Description:	Women who are pregnant or breastfeeding
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX11A00
2 h	Exclusion Number:	12
	Criterion Description:	Previous vaccination with any coronavirus vaccine
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX12A00
2.i	Exclusion Number:	13
	Criterion Description:	Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX13A01
2.j	Exclusion Number:	15
	Criterion Description:	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX14A01

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**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

2 k	Exclusion Number:	16
	Criterion Description:	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX15A01
2.1	Exclusion Number:	17
	Criterion Description:	Previous participation in other studies involving study intervention containing lipid nanoparticles
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX16A01
2.m	Exclusion Number:	22
	Criterion Description:	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX21A01

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**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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**Disposition - Screening**

1.	Date of Completion/Discontinuation/Death	Aug/21/2020
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:** 1226

**Subject No:** 12261338

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

**Form Comments**

**Medical History Details**

1.	Line/MH Number:	Not Applicable _____ [ ]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	Not Applicable _____ [ ]
	Start Date:	Not Applicable _____ //
	Ongoing:	Not Applicable _____

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**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Aug/21/2020
2.	Weight:	[42.5]
3.	Unit:	kg
4.	Height:	[152.0]
5.	Unit:	cm
6.	Body Mass Index:	[18.4]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[36.4]
	Unit:	C
	Temperature Location:	FOREHEAD

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**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/21/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

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**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** RANDOMIZATION

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Aug/21/2020
2.	Randomization Number:	[59919]
3.	Randomization Group:	[ ]

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/21/2020
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	[BP5T8K]
5.b	Sample ID	[BP5T8J]
5.c	Sample ID	[BP5T8H]
5.d	Sample ID	[BLCJ8C]
5.e	Sample ID	[BLCJ8B]

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**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261338

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

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

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/21/2020
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	[BP5TBF]
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090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** VACCINATION

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[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/21/2020 10:30
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[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:** 1226

**Subject No:** 12261338

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

**Form:** DATE OF VISIT

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/9/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[36.6]
	Unit:	C
	Temperature Location:	FOREHEAD

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/9/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

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**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1226

**Subject No:** 12261338

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

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

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[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	[BPWV97]
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090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** VACCINATION

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[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 12:01
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** DATE OF VISIT

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/7/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BPWZ5P]
5.b	Sample ID	[BRVB70]
5.c	Sample ID	[BRVB6Z]

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**Header Text:** C4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** DATE OF VISIT

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Mar/24/2021
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/24/2021
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	[BRGDSG]
5.b	Sample ID	[BSCX8H]
5.c	Sample ID	[BSCX8G]

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

**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:** 1226

**Subject No:** 12261338

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

**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:** 1226

**Subject No:** 12261338

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET  
on Nov/24/2020

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Date of Visit**

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

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_A
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19  
on Nov/24/2020

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Signs and Symptoms**

1.	Date of Assessment:	Nov/24/2020
2.	Date of First Symptom Started:	Nov/20/2020
3.	Symptoms Ongoing?	NO
	Date of Last Symptom Resolved:	Dec/25/2020

**Symptoms**

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

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19  
on Nov/24/2020

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

4.i	Symptoms:	VOMITING
	Was symptom present?	YES

**Symptoms - Other**

5.a	Symptoms - Other Text:	[Abdominal pain]
-----	------------------------	------------------

**Header Text:** C4591001

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

**Form:** MICROBIOLOGY SPECIMEN

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN  
on Nov/24/2020

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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**Microbiology Specimen**

1.	Actual Date of Collection:	Not Applicable _____ //	<a href="#">Comments</a>
2.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>
3.	Specimen Collection Location:	Not Applicable _____	<a href="#">Comments</a>
4.	Assay Code and Description:	Not Applicable _____	<a href="#">Comments</a>
5.	Device Type:	Not Applicable _____	<a href="#">Comments</a>
6.	Trade Name:	Not Applicable _____	<a href="#">Comments</a>
7.	Test Result:	Not Applicable _____	<a href="#">Comments</a>
8.	Comments/Findings/Details:	Not Applicable _____ [ ]	<a href="#">Comments</a>
9.	Trade Name Other, Specify:	Not Applicable _____ [ ]	<a href="#">Comments</a>

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Nov/24/2020

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[collected swab on site, recorded at swab pfe]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
on Nov/24/2020

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR60DW]
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090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION  
on Nov/24/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda**Subject No:** 12261338**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54[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: [2]
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

**Health Care Utilization Other**

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

**Health Care Utilization**

3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO
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**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** RESPIRATORY TREATMENT

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT  
on Nov/24/2020

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

**Form Status:** Not Started

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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**Respiratory Treatment**

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



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS  
on Nov/24/2020

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

[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?	NO
3.	Toxicity Grade:	2

**Header Text:** C4591001

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

**Form:** ILLNESS DETAILS - SEVERE

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

#	Category of Clinical Event :	Subcategory of Clinical Event t	Diagnosis Obtained d	Toxicity Grade e	Form Instance
1.					<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE  
on Nov/24/2020

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

**Form Status:** Not Started

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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**Illness Details**

1.	Category of Clinical Event:	
2.	Subcategory of Clinical Event:	
3.	Was a diagnosis obtained?	
4.	Toxicity Grade:	

Header Text: C4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	CLINICAL CHEMISTRY	[ ]	Nov/21/2020	BLOOD	<b>Sponsor-Defined Identifier</b>	<b>Test:</b>	<b>Result:</b>	<a href="#">Repeating Pages</a>
					329	C Reactive Protein_PX329	1.9	
					30	Alanine Aminotransferase_PX30	24	
					28	Aspartate Aminotransferase_PX28	20	
					35	Alkaline Phosphatase_PX35	[ ]	
					21	Bilirubin_PX21	[ ]	
					47	Blood Urea Nitrogen_PX47	28	
					48	Creatinine_PX48	0.75	

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Nov/24/2020

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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**Lab Chemistry Details**

1.	Lab Panel:	CLINICAL CHEMISTRY
2.	Laboratory Name and Address	[ ]
3.	Collection Date:	Nov/21/2020
4.	Specimen Type:	BLOOD

**Lab Result**

5.a	Sponsor ID:	[329]
	Test:	C Reactive Protein_PX329
	Result:	[1.9]
	Not Done:	
	LNMT	Low [0] High [6] Unit mg/L
5.b	Sponsor ID:	[30]
	Test:	Alanine Aminotransferase_PX30
	Result:	[24]
	Not Done:	
	LNMT	Low [0] High [31] Unit U/L

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Nov/24/2020

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

5.c	Sponsor ID:	[28]
	Test:	Aspartate Aminotransferase_PX28
	Result:	[20]
	Not Done:	
	LNMT	Low [0] High [31] Unit U/L
5.d	Sponsor ID:	[35]
	Test:	Alkaline Phosphatase_PX35
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit
5.e	Sponsor ID:	[21]
	Test:	Bilirubin_PX21
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Nov/24/2020

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

5.f	Sponsor ID:	[47]
	Test:	Blood Urea Nitrogen_PX47
	Result:	[28]
	Not Done:	
	LNMT	Low [15] High [40] Unit mg/dL

5.g	Sponsor ID:	[48]
	Test:	Creatinine_PX48
	Result:	[0.75]
	Not Done:	
	LNMT	Low [0.6] High [1.3] Unit mg/dL

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1. DELETED	HEMATOLOGY	[ ]	Nov/21/2020	BLOOD	<b>Sponsor-Defined Identifier</b>	<b>Test:</b>	<b>Result:</b>	<a href="#">Repeating Pages</a>
					1	Hemoglobin_PX1	15.40	
					2	Hematocrit_PX2	48.4	
					3	Erythrocytes_PX3	5.02	
					5	Platelets_PX5	0.293	
					7	Leukocytes_PX7	16300	
					608	Neutrophils_PX608	14197	
					609	Eosinophils_PX609	82	
					612	Monocytes_PX612	571	
					610	Basophils_PX610	0	
					611	Lymphocytes_PX611	1320	

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1

Form Version: 10-Oct-2020 16:02

Site No: 1226

Subject No: 12261338

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

#	Category for Lab Test	Vendor Name ( DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
2.	HEMATOLOGY	[]	Nov/21/2020	BLOOD	<b>Sponsor-Defined Identifier</b>	<b>Test:</b>	<b>Result:</b>	<a href="#">Repeating Pages</a>
					1	Hemoglobin_PX1	15	
					2	Hematocrit_PX2	47.6	
					3	Erythrocytes_PX3	4.98	
					5	Platelets_PX5	0.309	
					7	Leukocytes_PX7	14700	
					608	Neutrophils_PX608	13715	
					609	Eosinophils_PX609	29	
					612	Monocytes_PX612	221	
					610	Basophils_PX610	29	
					611	Lymphocytes_PX611	706	

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology on Nov/24/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Deleted, Frozen

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

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

**Laboratory Data Hematology**

1.	Lab Panel:	HEMATOLOGY
2.	Laboratory Name and Address	[ ]
3.	Collection Date:	Nov/21/2020
4.	Specimen Type:	BLOOD

**Lab Result**

5.a	Sponsor ID:	[+]
	Test:	Hemoglobin_PX1
	Result:	[15.40]
	Not Done:	
	LNMT	Low [11.3] High [16.3] Unit g/dL
5.b	Sponsor ID:	[2]
	Test:	Hematocrit_PX2
	Result:	[48.4]
	Not Done:	
	LNMT	Low [35] High [49] Unit %

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5.e	Sponsor ID:	[3]
	Test:	Erythrocytes_PX3
	Result:	[5.02]
	Not Done:	
	LNMT	Low [4.2] High [5.4] Unit 10 <sup>6</sup> /cu mm
5.d	Sponsor ID:	[5]
	Test:	Platelets_PX5
	Result:	[0.293]
	Not Done:	
	LNMT	Low [0.150] High [0.5] Unit 10 <sup>6</sup> /cu mm
5.e	Sponsor ID:	[7]
	Test:	Leukocytes_PX7
	Result:	[46300]
	Not Done:	
	LNMT	Low [4000] High [10000] Unit /uL
5.f	Sponsor ID:	[608]
	Test:	Neutrophils_PX608
	Result:	[44197]
	Not Done:	
	LNMT	Low [2500] High [7000] Unit /uL

5-g	Sponsor ID:	[609]
	Test:	Eosinophils_PX609
	Result:	[82]
	Not Done:	
	LNMT	Low [400] High [400] Unit /uL
5-h	Sponsor ID:	[612]
	Test:	Monocytes_PX612
	Result:	[571]
	Not Done:	
	LNMT	Low [200] High [900] Unit /uL
5-i	Sponsor ID:	[610]
	Test:	Basophils_PX610
	Result:	[0]
	Not Done:	
	LNMT	Low [0] High [100] Unit /uL
5-j	Sponsor ID:	[611]
	Test:	Lymphocytes_PX611
	Result:	[1320]
	Not Done:	
	LNMT	Low [4000] High [4400] Unit /uL

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/24/2020

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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**Laboratory Data Hematology**

1.	Lab Panel:	HEMATOLOGY
2.	Laboratory Name and Address	[ ]
3.	Collection Date:	Nov/21/2020
4.	Specimen Type:	BLOOD

**Lab Result**

5.a	Sponsor ID:	[1]
	Test:	Hemoglobin_PX1
	Result:	[15]
	Not Done:	
	LNMT	Low [11.3] High [16.3] Unit g/dL

5.b	Sponsor ID:	[2]
	Test:	Hematocrit_PX2
	Result:	[47.6]
	Not Done:	
	LNMT	Low [35] High [49] Unit %

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/24/2020

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

5.c	Sponsor ID:	[3]
	Test:	Erythrocytes_PX3
	Result:	[4.98]
	Not Done:	
	LNMT	Low [4.2] High [5.4] Unit 10^6/cu mm
5.d	Sponsor ID:	[5]
	Test:	Platelets_PX5
	Result:	[0.309]
	Not Done:	
	LNMT	Low [0.150] High [0.5] Unit 10^6/cu mm
5.e	Sponsor ID:	[7]
	Test:	Leukocytes_PX7
	Result:	[14700]
	Not Done:	
	LNMT	Low [4000] High [10000] Unit /uL

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/24/2020

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

5.f	Sponsor ID:	[608]
	Test:	Neutrophils_PX608
	Result:	[13715]
	Not Done:	
	LNMT	Low [2500] High [7000] Unit /uL
5.g	Sponsor ID:	[609]
	Test:	Eosinophils_PX609
	Result:	[29]
	Not Done:	
	LNMT	Low [100] High [400] Unit /uL
5.h	Sponsor ID:	[612]
	Test:	Monocytes_PX612
	Result:	[221]
	Not Done:	
	LNMT	Low [200] High [900] Unit /uL

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Nov/24/2020

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

5.i	Sponsor ID:	[610]
	Test:	Basophils_PX610
	Result:	[29]
	Not Done:	
	LNMT	Low [0] High [100] Unit /uL

5.j	Sponsor ID:	[611]
	Test:	Lymphocytes_PX611
	Result:	[706]
	Not Done:	
	LNMT	Low [1000] High [4000] Unit /uL

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**Header Text:** C4591001

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

**Form:** VITAL SIGNS - COVID

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

#	Date:	Vital Signs Details			Form Instance
1.	Nov/24/2020	<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>
		1	127	58	

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID  
on Nov/24/2020

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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**Vital Signs**

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

**Vital Signs Details**

2.a	Record Identifier:	1
	Systolic:	[127]
	Diastolic:	[58]
	Respiratory Rate in respirations/minute:	[12]
	Heart Rate in beats/minute:	[74]

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

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

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

#	Date:	Vital Signs Details		Form Instance
1.	Nov/24/2020	<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>
		1	99.0	

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
on Nov/24/2020

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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**Vital Signs**

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

**Vital Signs Details**

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[99.0]

**Header Text:** C4591001

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

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				<a href="#">Repeating Pages</a>

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS  
on Nov/24/2020

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

**Form Status:** Not Started

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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**Oxygenation Parameters**

1.	Date Time of Assessment:	//
2.	Arterial Blood Gases PaO2 (mmHg):	[ ]
3.	FiO2 (Fraction of Inhaled Oxygen):	[ ]

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS  
on Nov/24/2020

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

**Form Status:** Not Started

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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**Concomitant Medications**

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

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**Header Text:** C4591001

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

**Form:** IMAGING

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** IMAGING  
on Nov/24/2020

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

**Form Status:** Not Started

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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**Imaging**

1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Jan/13/2021

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

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/13/2021
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Jan/13/2021

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/13/2021
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	[BP9945]
5.b	Sample ID	[BSF2DR]
5.c	Sample ID	[BSF2DS]

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned - New Unscheduled Visit

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

**Unplanned Assessments**

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

**Header Text:** C4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** DISPOSITION - TREATMENT

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Disposition - Treatment**

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

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

**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:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

3.	COVID-19 Repeat Swab:	
----	-----------------------	--

**Header Text:** C4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VITAL SIGNS - TEMP

**Form Version:** 28-Mar-2021 02:28

**Form Status:** Not Started

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Not Started

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

**Lab Urinalysis**

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

**Lab Result**

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

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

**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?	

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

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

**Form Status:** Not Started

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

**Contact Outcome**

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

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 6

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

**Form Status:** Not Started

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

**Contact Outcome**

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



**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

**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:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

**Informed Consent - Asymptomatic Surveillance**

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

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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

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

**Site No:** 1226

**Subject No:** 12261338

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

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

**Form Status:** Not Started

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

**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, Locked, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/21/2021
2.	Erroneous Visit	

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** FURTHER VACCINATION CONFIRMATION

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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**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
----	---	--

Header Text: C4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Body pain	Aug/22/2020 UNK: UNK	NO End Date Time:  Aug/23/2020 UNK:UNK	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	Fever	Aug/22/2020 UNK: UNK	NO End Date Time:  Aug/23/2020 UNK:UNK	<a href="#">Repeating Pages</a>
3.	ADVERSE EVENT	3	Pain at injection site	Aug/22/2020 UNK: UNK	NO End Date Time:  Aug/23/2020 UNK:UNK	<a href="#">Repeating Pages</a>
4.	ADVERSE EVENT	4	Pain at injection site	Sep/9/2020 18:00	NO End Date Time:  Sep/10/2020 UNK:UNK	<a href="#">Repeating Pages</a>
5.	ADVERSE EVENT	5	chills	Sep/10/2020 UNK: UNK	NO End Date Time:  Sep/10/2020 UNK:UNK	<a href="#">Repeating Pages</a>
6.	ADVERSE EVENT	6	Gastroenterocolitis	Nov/20/2020 22:00	NO End Date Time:  Nov/29/2020 UNK:UNK	<a href="#">Repeating Pages</a>

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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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)	[Body pain]
4.	Start Date Time:	Aug/22/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/23/2020 UNK:UNK
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:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fever]
4.	Start Date Time:	Aug/22/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/23/2020 UNK:UNK
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:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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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)	[Pain at injecton site]
4.	Start Date Time:	Aug/22/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/23/2020 UNK:UNK
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:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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

**Header Text:** C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1226**Subject No:** 12261338**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:54

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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)	[Pain at injection site]
4.	Start Date Time:	Sep/9/2020 18:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/10/2020 UNK:UNK
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:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

**Header Text:** C4591001

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**Site No:** 1226

**Subject No:** 12261338

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

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

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**Subject No:** 12261338

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

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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)	[chills]
4.	Start Date Time:	Sep/10/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/10/2020 UNK:UNK
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:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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

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**Header Text:** C4591001

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**Subject No:** 12261338

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

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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)	[Gastroenterocolitis]
4.	Start Date Time:	Nov/20/2020 22:00
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/29/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? NO  Did this serious event require or prolong hospitalization? YES  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? NO  Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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**Site No:** 1226

**Subject No:** 12261338

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

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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: [Food poisoning]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	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	[2020463228]

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**Header Text:** C4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

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**Medication Error**

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

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**Header Text:** C4591001

**Visit:** Logs

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
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**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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**Concomitant Medications**

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

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**Header Text:** C4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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**Concomitant Medications**

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

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**Header Text:** C4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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**Radiation Treatment**

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

**Header Text:** C4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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

**Header Text:** C4591001

**Visit:** UNPLANNED\_BOOSTER\_CONTACT - **Form:** DATE OF VISIT

Unscheduled

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

**Form Status:** Not Started

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
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**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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

**Header Text:** C4591001

**Visit:** UNPLANNED\_BOOSTER\_CONTACT - **Form:** BOOSTER DOSE TRIGGER FORM  
Unscheduled

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

**Form Status:** Not Started

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

**Booster Dose Trigger Form**

1.	Select appropriate response - Will the participant return for consent/eligibility assessment for the booster dose visit?	
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**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** TREATMENT UNBLINDED

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Jan/22/2021
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:** 1226

**Subject No:** 12261338

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

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

**Withdrawal Of Consent**

1.	Withdrawal of Consent Date :	//
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**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

**Death Details**

1.	Date of Collection / Notification of Death:	//
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**Cause of Death**

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

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Subject Status**

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

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** CASEBOOK SIGNATURE FORM

**Form Status:** Data Complete, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Casebook Signature Form**

1.	Casebook Signature	<a href="#">Click Here to Enable</a>
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**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

[Audit Trail](#)

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
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090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** GENERAL MEDICAL HISTORY - Comments

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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Item	Date	User	Comment
Form	Aug-21-2020 14:44:49 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Nov/24/2020

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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Item	Date	User	Comment
Form	Nov-25-2020 09:30:47 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Nov/24/2020

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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Item	Date	User	Comment
1	Nov-25-2020 09:30:47 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Nov/24/2020

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
2	Nov-25-2020 09:30:47 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Nov/24/2020

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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Item	Date	User	Comment
3	Nov-25-2020 09:30:47 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Nov/24/2020

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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Item	Date	User	Comment
4	Nov-25-2020 09:30:47 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Nov/24/2020

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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Item	Date	User	Comment
5	Nov-25-2020 09:30:47 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Nov/24/2020

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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Item	Date	User	Comment
6	Nov-25-2020 09:30:47 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Nov/24/2020

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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Item	Date	User	Comment
7	Nov-25-2020 09:30:47 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Nov/24/2020

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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Item	Date	User	Comment
8	Nov-25-2020 09:30:47 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments  
on Nov/24/2020

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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Item	Date	User	Comment
9	Nov-25-2020 09:30:47 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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

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Item	Date	User	Comment
Form	Nov-25-2020 09:47:28 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The WBC differentials are in absolute values. They also are in "/cu mm" in the exam results, so we reported in microliter because the relation is 1/1.

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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Item	Date	User	Comment
Form	Nov-25-2020 09:51:43 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	The WBC differentials are in absolute values. They also are in "/cu mm" in the exam results, so we reported in microliter because the relation is 1/1.

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261338

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

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

**Form Status:** Data Complete, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Mar-25-2021 08:05:30 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated

**Affidavit:**

N/A

Cristiano Zerbini	Approved	Mar-24-2021 11:13:45 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, CristianoZerbini, 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-24-2021 10:39:48 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

Cristiano Zerbini	Approved	Feb-11-2021 10:47:49 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, CristianoZerbini, 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.

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

(b) (6)	N/A	Feb-09-2021 12:29:10 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

Cristiano Zerbini	Approved	Feb-05-2021 10:12:59 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Feb-01-2021 11:26:39 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

Cristiano Zerbini	Approved	Jan-30-2021 11:22:34 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, Cristiano Zerbini, 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-23-2021 10:07:52 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

Cristiano Zerbini	Approved	Jan-21-2021 16:13:55 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, Cristiano Zerbini, 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-13-2021 15:32:20 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

Cristiano Zerbini	Approved	Dec-11-2020 09:09:41 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Dec-03-2020 13:44:38 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

Cristiano Zerbini	Approved	Nov-26-2020 16:21:45 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

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

**Form Status:** Data Complete, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

**Affidavit:**

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

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

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

(b) (6)	N/A	Nov-23-2020 15:22:56 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

Cristiano Zerbini	Approved	Oct-21-2020 17:27:30 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, CristianoZerbini, 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.

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** COHORT SELECTION - eCRF Audit Trail History

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Aug-21-2020 14:43:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 30 JUN 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-21-2020 14:43:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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*I. Consent Was:*

Date	Location	User	Value	Reason
Aug-21-2020 14:43:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Aug/21/2020	Initial Entry



Header Text: C4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1226

Subject No: 12261338

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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**1. Subject ID**

Date	Location	User	Value	Reason
Aug-21-2020 14:42:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12261338	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-21-2020 14:42:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1989	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-21-2020 14:43:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Aug-21-2020 14:43:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Dec-04-2020 12:51:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-04-2020 07:37:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Other
Dec-03-2020 18:23:41	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Subject is

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** DEMOGRAPHY - eCRF Audit Trail History

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

(UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)		indicated on Demography CRF as Asian, please specify further racial designation as Japanese (i.e. defined as all four grandparents born in Japan, of Japanese ancestry), or Other.
Aug-21-2020 14:43:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASIAN	Initial Entry

**6. Racial Designation:**

Date	Location	User	Value	Reason
Dec-10-2020 21:40:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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*1. Date of Visit*

Date	Location	User	Value	Reason
Aug-21-2020 14:43:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/21/2020	Initial Entry

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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*I.a*

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Inclusion Number:</b> <b>Criterion Description:</b> Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage) <b>Criterion Met?:</b> <b>Criterion ID:</b> IN01A00 <b>Use only:</b> (For Pfizer use only):	Initial Entry

*I.a Inclusion Number:*

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

*I.a Criterion Description:*

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive,	Initial Entry

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

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Subject Initials: ---

Generated By: (b) (4)

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			or 18 and 85 years, inclusive, at randomization (dependent upon study stage)	
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*I.a Criterion met?*

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

*I.a Criterion ID: (For Pfizer use only)*

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> IN01A00	Initial Entry

*I.b*

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Inclusion Number:</b> <b>Criteria</b> Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures <b>Criteria met?:</b> <b>Criteria ID:</b> IN02A00 <b>(For Pfizer use only):</b>	Initial Entry

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Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

***1.b Inclusion Number:***

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

***1.b Criterion Description:***

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures	Initial Entry

***1.b Criterion met?***

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.b Criterion ID: (For Pfizer use only)***

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> IN02A00	Initial Entry

***1.c***

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Inclusion Number:	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

			<p><b>Criteria</b> Healthy participants who <b>on Des</b> are determined by medical <b>criteria</b> history, physical examination, <b>n:</b> ation, and clinical judgment of the investigator to be eligible for inclusion in the study</p> <p><b>Criteria</b> YES <b>on met</b> <b>?:</b></p> <p><b>Criteria</b> IN03A00 <b>on ID:</b> <b>(For Pfizer use only</b> <b>):</b></p>	
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Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

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**I.c Inclusion Number:**

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

**I.c Criterion Description:**

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study	Initial Entry

**I.c Criterion met?**

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.c Criterion ID: (For Pfizer use only)**

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> IN03A00	Initial Entry

**I.d**

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Inclusion Number: 4	Initial Entry

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**Header Text:** C4591001

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**Site No:** 1226

**Subject No:** 12261338

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

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

			<p><b>Criteria</b> Capable of giving person  <b>on Des</b> al signed informed conse  <b>criptio</b> nt, which includes compl  <b>n:</b> iance with the requireme  nts and restrictions listed  in the ICD and in this pro  tocol</p> <p><b>Criteria</b> YES  <b>on met</b>  ?:</p> <p><b>Criteria</b> IN04A00  <b>on ID:</b>  <b>(For P</b>  <b>fizer u</b>  <b>se only</b>  <b>):</b></p>	
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Header Text: C4591001

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Subject Initials: ---

Generated By: (b) (4)

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**1.d Inclusion Number:**

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4	Initial Entry

**1.d Criterion Description:**

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol	Initial Entry

**1.d Criterion met?**

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.d Criterion ID: (For Pfizer use only)**

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> IN04A00	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclus 1 ion Nu mber:</b>	Initial Entry

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**Header Text:** C4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 21-Aug-2020 02:50**Site No:** 1226**Subject No:** 12261338**Generated By:** (b) (4)**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:54

			<b>Criterion Description:</b> Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation  <b>Criterion met?:</b> NO  <b>Criterion ID:</b> EX01A00 <b>(For Pfizer use only):</b>	
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**2.a Exclusion Number:**

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Criterion Description:**

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation	Initial Entry

**2.a Criterion met?**

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a Criterion ID: (For Pfizer use only)**

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Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX01A00	Initial Entry

2.b

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusion Number:</b> <b>Criterion Description:</b> Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV) <b>Criterion met?:</b> NO <b>Criterion ID: (For Pfizer use only):</b> EX02A00	Initial Entry

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Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

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2.b Exclusion Number:

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2	Initial Entry

2.b Criterion Description:

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)	Initial Entry

2.b Criterion met?

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.b Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> EX02A00	Initial Entry

2.c

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Exclusion Number: 3	Initial Entry

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**Header Text:** C4591001

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

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**Generated Time (GMT):** 29-Mar-2021 13:54

			<p><b>Criteria History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)</b></p> <p><b>Criteria NO</b></p> <p><b>on met</b></p> <p><b>?:</b></p> <p><b>Criteria EX03A00</b></p> <p><b>on ID:</b></p> <p><b>(For Pfizer use only):</b></p>	
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Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

2.c Exclusion Number:

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

2.c Criterion Description:

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)	Initial Entry

2.c Criterion met?

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.c Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX03A00	Initial Entry

2.d

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusion Number:</b> 4 <b>Criterion Description:</b> Receipt of medications intended to prevent COVID-19	Initial Entry

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Header Text: C4591001

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Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			<b>Criterion met?</b> <b>Criterion ID</b> EX04A00 <b>: (For Pfizer use only):</b>	
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**2.d Exclusion Number:**

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4	Initial Entry

**2.d Criterion Description:**

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Receipt of medications intended to prevent COVID-19	Initial Entry

**2.d Criterion met?**

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.d Criterion ID: (For Pfizer use only)**

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX04A00	Initial Entry

**2.e**

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclusion 8 on Nu	Initial Entry

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**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

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			<p><b>mber:</b></p> <p><b>Criteria on Description:</b> Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination</p> <p><b>Criteria met?:</b> NO</p> <p><b>Criteria ID:</b> EX08A00</p> <p><b>(For Pfizer use only):</b></p>	
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Header Text: C4591001

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Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

2.e Exclusion Number:

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 8	Initial Entry

2.e Criterion Description:

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Immunocompromised individuals with known or suspected immuno deficiency, as determined by history and/or laboratory/physical examination	Initial Entry

2.e Criterion met?

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.e Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX08A00	Initial Entry

2.f

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclusion Number: 10	Initial Entry

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**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

			<p><b>Criterion Description:</b> Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection</p> <p><b>Criterion Met:</b> NO</p> <p><b>Criterion ID:</b> EX10A00 (For Pfizer use only)</p>	
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Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

2.f Exclusion Number:

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 10	Initial Entry

2.f Criterion Description:

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection	Initial Entry

2.f Criterion met?

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.f Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX10A00	Initial Entry

2.g

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusion Number:</b> 11 <b>Criterion Description:</b> Women who are pregnant or breastfeeding	Initial Entry

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Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			Criterion met NO ?: Criterion ID: ( EX11A00 For Pfizer use only):	
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2.g Exclusion Number:

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 11	Initial Entry

2.g Criterion Description:

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Women who are pregnant or breastfeeding	Initial Entry

2.g Criterion met?

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.g Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX11A00	Initial Entry

2.h

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclusion Number:	Initial Entry

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Header Text: C4591001

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Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

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			<b>Criterion Description:</b> Previous vaccination with any coronavirus vaccine <b>Criterion met?:</b> NO <b>Criterion ID:</b> EX12A00 <b>(For Pfizer use only):</b>
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**2.h Exclusion Number:**

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 12	Initial Entry

**2.h Criterion Description:**

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Previous vaccination with any coronavirus vaccine	Initial Entry

**2.h Criterion met?**

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.h Criterion ID: (For Pfizer use only)**

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX12A00	Initial Entry

**2.i**

Date	Location	User	Value	Reason
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090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

<p>Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p><b>Data Entry:</b> <b>Exclusion Number:</b> 13 <b>Criteria Description:</b> Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids <b>Criteria met?:</b> NO <b>Criteria ID: (For Pfizer use only):</b> EX13A01</p>	<p>Initial Entry</p>
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Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

2.i Exclusion Number:

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 13	Initial Entry

2.i Criterion Description:

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids	Initial Entry

2.i Criterion met?

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.i Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> EX13A01	Initial Entry

2.j

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Exclusion Number: 15	Initial Entry

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**Site No:** 1226

**Subject No:** 12261338

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

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

			<p><b>Criteria on Description:</b> Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study</p> <p><b>Criteria met?:</b> NO</p> <p><b>Criteria ID:</b> EX14A01 (For Pfizer use only)</p> <p>:</p>	
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Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

2.j Exclusion Number:

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 15	Initial Entry

2.j Criterion Description:

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study	Initial Entry

2.j Criterion met?

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.j Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX14A01	Initial Entry

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

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

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2.k

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusion Number:</b> 16 <b>Criteria Description:</b> Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation <b>Criteria met?:</b> NO <b>Criteria ID:</b> EX15A01 <b>For Pfizer use only):</b>	Initial Entry

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Header Text: C4591001

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Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

2.k Exclusion Number:

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 16	Initial Entry

2.k Criterion Description:

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation	Initial Entry

2.k Criterion met?

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.k Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX15A01	Initial Entry

2.l

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclusion Number:	Initial Entry

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

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			<b>Criterion Description:</b> Previous participation in other studies involving study intervention containing lipid nanoparticles  <b>Criterion met?:</b> NO  <b>Criterion ID: (For Pfizer use only):</b> EX16A01	
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2.1 Exclusion Number:

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 17	Initial Entry

2.1 Criterion Description:

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Previous participation in other studies involving study intervention containing lipid nanoparticles	Initial Entry

2.1 Criterion met?

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.1 Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX16A01	Initial Entry

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**Header Text:** C4591001

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

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**Site No:** 1226

**Subject No:** 12261338

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

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

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2.m

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b></p> <p><b>Exclusion Number:</b> 22</p> <p><b>Criteria:</b> Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members</p> <p><b>Criterion ID:</b> EX21A01</p> <p><b>Use only:</b> (For Pfizer use only):</p>	Initial Entry

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Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

**2.m Exclusion Number:**

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 22	Initial Entry

**2.m Criterion Description:**

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members	Initial Entry

**2.m Criterion met?**

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.m Criterion ID: (For Pfizer use only)**

Date	Location	User	Value	Reason
Aug-21-2020 14:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX21A01	Initial Entry

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**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Aug-21-2020 14:44:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/21/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-21-2020 14:44:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Aug-21-2020 14:44:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)



Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1226

Subject No: 12261338

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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**1. Date:**

Date	Location	User	Value	Reason
Aug-21-2020 14:45:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/21/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-21-2020 14:45:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 42.5	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-21-2020 14:45:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Aug-21-2020 14:45:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 152.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Aug-21-2020 14:45:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
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090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1226

Subject No: 12261338

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

Aug-21-2020 14:45:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 18.4	Initial Entry
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7.a

Date	Location	User	Value	Reason
Aug-21-2020 14:45:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 36.4 <b>Temperature Unit:</b> C <b>Temperature Location::</b> FOREHEAD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-21-2020 14:45:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-21-2020 14:45:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.4	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-21-2020 14:45:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-21-2020 14:45:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FOREHEAD	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Aug-21-2020 14:46:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Aug-21-2020 14:46:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Aug-21-2020 14:46:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aug/21/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Aug-21-2020 14:46:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Aug-21-2020 14:46:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
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090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Aug-21-2020 14:46:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 113 <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> NEGATIVE <b>Not Done::</b>	Initial Entry
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**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Aug-21-2020 14:46:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Aug-21-2020 14:46:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Aug-21-2020 14:46:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** RANDOMIZATION - eCRF Audit Trail History

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Aug-21-2020 14:48:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/21/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-21-2020 14:48:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 59919	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (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: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-21-2020 15:31:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-21-2020 15:31:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-21-2020 15:31:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-21-2020 15:31:20 (UTC-03:00) City of Buenos Aires	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 15:31:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection: Aug/21/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-21-2020 15:31:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP5T8K	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (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: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.a Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 15:31:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP5T8K	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-21-2020 15:31:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP5T8J	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 15:31:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP5T8J	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-21-2020 15:31:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP5T8H	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 15:31:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP5T8H	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-21-2020 15:31:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BLCJ8C	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (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:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

**5.d Sample ID**

Date	Location	User	Value	Reason
Aug-21-2020 15:31:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLCJ8C	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Aug-21-2020 15:31:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BLCJ8B	Initial Entry

**5.e Sample ID**

Date	Location	User	Value	Reason
Aug-21-2020 15:31:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLCJ8B	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)



Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-21-2020 15:32:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-21-2020 15:32:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-21-2020 15:32:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-21-2020 15:32:03 (UTC-03:00) City of Buenos Aires	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 15:32:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection: Aug/21/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-21-2020 15:32:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP5TBF	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261338

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

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

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-21-2020 15:32:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP5TBF	Initial Entry

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261338

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Aug-21-2020 14:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Aug-21-2020 14:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-21-2020 14:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Aug-21-2020 14:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/21/2020 10:30	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-21-2020 14:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
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090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** VACCINATION - eCRF Audit Trail History

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

Aug-21-2020 14:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry
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**7. Route:**

Date	Location	User	Value	Reason
Aug-21-2020 14:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Aug-21-2020 14:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-21-2020 14:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Aug-21-2020 14:50:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-09-2020 13:09:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/9/2020	Initial Entry

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 21-Aug-2020 02:51

Site No: 1226

Subject No: 12261338

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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**I. Date:**

Date	Location	User	Value	Reason
Sep-09-2020 13:09:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/9/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-09-2020 13:09:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 36.6 <b>Temperature Unit:</b> C <b>Temperature Location:</b> FOREHE AD	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-09-2020 13:09:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-09-2020 13:09:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.6	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-09-2020 13:09:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

**2.a Temperature Location:**

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Sep-09-2020 13:09:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FOREHEAD	Initial Entry



Header Text: C4591001

Visit: V2\_VAX2\_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-09-2020 13:10:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Sep-09-2020 13:10:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Sep-09-2020 13:10:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/9/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Sep-09-2020 13:10:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Sep-09-2020 13:10:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
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090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Sep-09-2020 13:10:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 113 <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> NEGATIVE <b>Not Done::</b>	Initial Entry
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-09-2020 13:10:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-09-2020 13:10:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-09-2020 13:10:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-10-2020 09:08:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-10-2020 09:08:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-10-2020 09:08:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-10-2020 09:08:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-10-2020 09:08:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection: Sep/9/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-10-2020 09:08:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPWV97	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1226

**Subject No:** 12261338

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

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

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-10-2020 09:08:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPWV97	Initial Entry

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261338

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-09-2020 13:10:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-09-2020 13:10:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-09-2020 13:10:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-09-2020 13:10:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/9/2020 12:01	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-09-2020 13:10:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
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090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** VACCINATION - eCRF Audit Trail History

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

Sep-09-2020 13:10:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry
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**7. Route:**

Date	Location	User	Value	Reason
Sep-09-2020 13:10:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-09-2020 13:10:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 13:10:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-08-2020 07:46:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/7/2020	Transcription Error
Oct-08-2020 07:31:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/8/2020	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (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:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject No:** 12261338**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-08-2020 09:08:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-08-2020 09:08:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-08-2020 09:08:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-08-2020 09:08:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-08-2020 09:08:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/7/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-08-2020 09:08:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPWZ5P	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: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

		(b) (4), (b) (6)		
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5.a Sample ID

Date	Location	User	Value	Reason
Oct-08-2020 09:08:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPWZ5P	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-08-2020 09:08:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRVB70	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-08-2020 09:08:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRVB70	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-08-2020 09:08:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRVB6Z	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-08-2020 09:08:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRVB6Z	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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*1. Date of Visit*

Date	Location	User	Value	Reason
Mar-26-2021 04:23:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	PDQ: Date of visit at V4_MONTH6_L is out of window for 7 days from V2_VAX2_L DOV or V2 Vaccination date. Please verify and update. Else, confirm in query response appropriately. (b) (4)
Mar-24-2021 10:39:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/24/ 2021	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (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: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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**1. Data Origin**

Date	Location	User	Value	Reason
Mar-25-2021 08:05:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-25-2021 08:05:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-25-2021 08:05:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-25-2021 08:05:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-25-2021 08:05:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Mar/24/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-25-2021 08:05:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BRGDSG	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (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: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.a Sample ID

Date	Location	User	Value	Reason
Mar-25-2021 08:05:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRGDSG	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-25-2021 08:05:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BSCX8H	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-25-2021 08:05:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BSCX8H	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-25-2021 08:06:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BSCX8G	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-25-2021 08:06:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BSCX8G	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Nov/24/2020**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject No:** 12261338**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54[Back to Form](#)**1. Date of Visit**

Date	Location	User	Value	Reason
Nov-25-2020 17:43:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-25-2020 09:29:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Nov-25-2020 09:28:41 (UTC-03:00) City of Buenos Aires	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.
Nov-25-2020 09:28:41 (UTC-03:00) City of Buenos Aires	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.
Nov-25-2020 09:28:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/24/2020	Initial Entry

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

Date	Location	User	Value	Reason
Nov-25-2020 09:28:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1226**Subject No:** 12261338**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:54[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Nov-25-2020 09:29:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/24/2020	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Nov-25-2020 09:29:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/20/2020	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Jan-13-2021 15:32:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Symptom Resolved:  Dec/25/2020	New Information
Nov-25-2020 09:29:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.a**

Date	Location	User	Value	Reason
Nov-25-2020 09:29:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b> NO	Initial Entry

**4.a Symptoms:**

Date	Location	User	Value	Reason
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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Nov-25-2020 09:29:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> FEVER	Initial Entry
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4.a Was symptom present?

Date	Location	User	Value	Reason
Nov-25-2020 09:29:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Nov-25-2020 09:29:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms NEW OR INCREASED COUGH Symptom NO Present:	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Nov-25-2020 09:29:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Nov-25-2020 09:29:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Nov-25-2020 09:29:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			REATH Symptom Present: NO	
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4.c Symptoms:

Date	Location	User	Value	Reason
Nov-25-2020 09:29:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Nov-25-2020 09:29:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Nov-25-2020 09:29:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms: CHILLS Symptom Present: NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Nov-25-2020 09:29:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Nov-25-2020 09:29:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

**Site No:** 1226

**Subject No:** 12261338

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

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

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

**4.e**

Date	Location	User	Value	Reason
Nov-25-2020 09:29:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptom NEW OR INCREASED MUSCLE PAIN Symptom NO Present:	Initial Entry

**4.e Symptoms:**

Date	Location	User	Value	Reason
Nov-25-2020 09:29:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED MUSCLE PAIN	Initial Entry

**4.e Was symptom present?**

Date	Location	User	Value	Reason
Nov-25-2020 09:29:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.f**

Date	Location	User	Value	Reason
Nov-25-2020 09:29:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms NEW LOSS OF TASTE OR SMELL Symptom NO Present:	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

4.f Symptoms:

Date	Location	User	Value	Reason
Nov-25-2020 09:29:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Nov-25-2020 09:29:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Nov-25-2020 09:29:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom NEW OR INCREASED SORE THROAT Symptom NO Present:	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Nov-25-2020 09:29:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Nov-25-2020 09:29:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.h

Date	Location	User	Value	Reason
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090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Nov/24/2020

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

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

Nov-25-2020 09:29:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> DIARRHE A <b>Symptom Present</b> YES :	Initial Entry
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**4.h Symptoms:**

Date	Location	User	Value	Reason
Nov-25-2020 09:29:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

**4.h Was symptom present?**

Date	Location	User	Value	Reason
Nov-25-2020 09:29:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.i**

Date	Location	User	Value	Reason
Nov-25-2020 09:29:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITIN G <b>Symptom Present</b> YES :	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

**4.i Symptoms:**

Date	Location	User	Value	Reason
Nov-25-2020 09:29:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> VOMITING	Initial Entry

**4.i Was symptom present?**

Date	Location	User	Value	Reason
Nov-25-2020 09:29:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-25-2020 09:30:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms - Other: Abdominal pain	Initial Entry

**5.a Symptoms - Other Text:**

Date	Location	User	Value	Reason
Nov-25-2020 09:30:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Abdominal pain	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Nov/24/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Nov-25-2020 09:30:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Nov-25-2020 09:30:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Nov-25-2020 09:30:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Nov-25-2020 09:30:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Nov-25-2020 09:30:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Not Applicable	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
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090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Nov/24/2020

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

Nov-25-2020 09:30:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**7. Test Result:**

Date	Location	User	Value	Reason
Nov-25-2020 09:30:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**8. Comments/Findings/Details:**

Date	Location	User	Value	Reason
Nov-25-2020 09:30:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**9. Trade Name Other, Specify:**

Date	Location	User	Value	Reason
Nov-25-2020 09:30:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

**Site No:** 1226

**Subject No:** 12261338

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

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

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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**1. Data Origin**

Date	Location	User	Value	Reason
Nov-25-2020 17:43:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-25-2020 17:43:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-25-2020 17:43:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Nov-25-2020 17:43:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> collected swab on site, recorded at swab pfe	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

**Site No:** 1226

**Subject No:** 12261338

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

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

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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**1. Data Origin**

Date	Location	User	Value	Reason
Nov-25-2020 17:43:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-25-2020 17:43:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-25-2020 17:44:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-25-2020 17:44:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/24/2020	Transcription Error
Nov-25-2020 17:43:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Nov-25-2020 17:43:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-25-2020 17:43:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date of Collection 25/Nov/2020 is different from Date

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

				of Visit 24/Nov /2020. Please review and update as appropriate, else clarify.
Nov-25-2020 17:43:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/25/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-25-2020 17:43:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR60DW	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Nov-25-2020 17:43:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR60DW	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/24/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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**I.a**

Date	Location	User	Value	Reason
Nov-25-2020 09:32:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIALIST <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

**I.a Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Nov-25-2020 09:32:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SPECIALIST	Initial Entry

**I.a Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Nov-25-2020 09:32:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**I.b**

Date	Location	User	Value	Reason
Nov-25-2020 09:32:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENCY ROOM <b>Occurrence of Visits or Contacts:</b> YES <i>Number of Visits or Contacts:</i> 2	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/24/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-25-2020 09:32:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

***1.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-25-2020 09:32:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Number of Visits or Contacts:</i>  2	Initial Entry

***1.c***

Date	Location	User	Value	Reason
Nov-25-2020 09:32:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

***1.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-25-2020 09:32:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

***1.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-25-2020 09:32:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/24/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

*I.d*

Date	Location	User	Value	Reason
Nov-25-2020 09:32:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry

*I.d Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Nov-25-2020 09:32:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> URGENT CARE	Initial Entry

*I.d Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Nov-25-2020 09:32:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*I.e*

Date	Location	User	Value	Reason
Nov-25-2020 09:32:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/24/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject No:** 12261338**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-25-2020 09:32:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> TELEPHONE CONSULTATIO N	Initial Entry

***1.e Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-25-2020 09:32:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.f***

Date	Location	User	Value	Reason
Nov-25-2020 09:32:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTH ER <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

***1.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-25-2020 09:32:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

***1.f Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Nov-25-2020 09:32:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Nov/24/2020

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

Nov-25-2020 09:32:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History  
on Nov/24/2020

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Nov-25-2020 09:33:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID-19 ILLNES S	Initial Entry

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

Date	Location	User	Value	Reason
Nov-25-2020 09:33:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Nov-25-2020 09:33:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Audit Trail

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

**Form Status:**

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> CLINICAL CHEMISTRY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/21/2020	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLOOD	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 329 <b>Test::</b> C Reactive Protein_PX329 <b>Result::</b> 1.9 <b>Not Done::</b> <b>Lab Normal Range:</b> Low 0 High 6 Unit mg/L	Initial Entry

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 329	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> C Reactive Protein_PX329	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1.9	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <i>Low</i> 0  <i>High</i> 6  <i>Unit</i> mg/L	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> <b>Sponsor-Defined Identifier:</b> 30	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

**Site No:** 1226

**Subject No:** 12261338

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

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

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

			<b>Test::</b> Alanine Aminotransferase_PX30	
			<b>Result::</b> 24	
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b> <i>Low</i>	
			0	
			<i>High</i>	
			31	
			<i>Unit</i>	
			U/L	

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.b Sponsor ID:

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Alanine Aminotransferase_PX30	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 24	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <i>Low</i> 0  <i>High</i> 31  <i>Unit</i> U/L	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> <b>Sponsor-Defined Identifier:</b>	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

**Site No:** 1226

**Subject No:** 12261338

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

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

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

			<b>Test::</b>	Aspartate Aminotransferase_PX28	
			<b>Result::</b>	20	
			<b>Not Done::</b>		
			<b>Lab Normal Range:</b>	<i>Low</i>	
				0	
				<i>High</i>	
				31	
				<i>Unit</i>	
				U/L	

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

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Form Status: Data Complete, Frozen, Verified

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Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.c Sponsor ID:

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 28	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aspartate Aminotransferase_PX 28	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 20	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <i>Low</i> 0  <i>High</i> 31  <i>Unit</i> U/L	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> <b>Sponsor-Define d Identifier:</b> 35	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

			<b>Test::</b> Alkaline Phosphatase_PX35	
			<b>Result::</b>	
			<b>Not Done::</b> NOT DONE	
			<b>Lab Normal Range:</b>	

**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 35	Initial Entry

**5.d Test:**

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Alkaline Phosphatase_PX35	Initial Entry

**5.d Not Done:**

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Defined Identifier: Bilirubin_P X21 <b>Test::</b> Bilirubin_P X21 <b>Result::</b> <b>Not Done::</b> NOT DONE <b>Lab Normal Range:</b>	Initial Entry

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.e Sponsor ID:

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 21	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Bilirubin_PX21	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT DONE	Initial Entry

5.f

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Sponsor-Define 47 d Identifier: Test:: Blood Urea Nitr ogen_PX47 Result:: 28 Not Done:: Lab Normal Range: Low 15 High 40 Unit mg/dL	Initial Entry

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

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Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.f Sponsor ID:

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 47	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Blood Urea Nitrogen_PX47	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 28	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <i>Low</i> 15  <i>High</i> 40  <i>Unit</i> mg/dL	Initial Entry

5.g

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> <b>Sponsor-Defined Identifier:</b> 48	Initial Entry

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

**Site No:** 1226

**Subject No:** 12261338

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

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

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**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

			<b>Test::</b>	Creatinine_P X48	
			<b>Result::</b>	0.75	
			<b>Not Done::</b>		
			<b>Lab Normal Range</b>	<i>Low</i>	
			:	0.6	
				<i>High</i>	
				1.3	
				<i>Unit</i>	
				mg/dL	

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

**5.g Sponsor ID:**

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 48	Initial Entry

**5.g Test:**

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Creatinine_PX48	Initial Entry

**5.g Result:**

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 0.75	Initial Entry

**5.g LNMT**

Date	Location	User	Value	Reason
Nov-25-2020 09:55:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <i>Low</i> 0.6  <i>High</i> 1.3  <i>Unit</i> mg/dL	Initial Entry

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Audit Trail

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

**Form Status:**

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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Date	Location	User	Value	Reason
Feb-09-2021 12:29:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	Query response "Per completion guidelines, If multiple values were recorded on a single day, the most abnormal should be recorded, Please review the collection date 21Nov2020 and update as applicable."
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> HEMATOLOGY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Feb-11-2021 04:55:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	data deleted
Feb-09-2021 12:29:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Query response "Per completion guidelines, If multiple values were recorded on a single day, the most abnormal should be recorded, Please review the collection date 21Nov2020 and update as applicable."
Feb-09-2021 09:07:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Per completion guidelines, If multiple values were recorded on a single day, the most abnormal should be recorded, Please review the collection date 21Nov2020 and update as applicable. Else clarify.
Nov-25-2020 15:22:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

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Buenos Aires		(b) (4), (b) (6)		
Nov-25-2020 12:13:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	data entry correction updated
Nov-25-2020 10:57:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	According to source document, Hemoglobin_PX1 is 15.40 g/dl; Could you please clarify and update if appropriate? Thank you.
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/21/2020	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLOOD	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-25-2020 12:13:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 1 <b>Test::</b> Hemoglobi n_PX1 <b>Result::</b> 15.40 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 11.3 <i>High</i> 16.3 <i>Unit</i> g/dL	data entry correction
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 1 <b>Test::</b> Hemoglobi n_PX1 <b>Result::</b> 15.5	Initial Entry

			<b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 11.3  <i>High</i> 16.3  <i>Unit</i> g/dL	
<b>5.a Sponsor ID:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry
<b>5.a Test:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hemoglobin_PX1	Initial Entry
<b>5.a Result:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Nov-25-2020 12:13:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 15.40	data entry correction
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 15.5	Initial Entry
<b>5.a LNMT</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 11.3  <i>High</i> 16.3  <i>Unit</i> g/dL	Initial Entry
<b>5.b</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>

Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Hematocrit_ PX2 <b>Result::</b> 48.4 <b>Not Done::</b> <b>Lab Normal Range</b> <i>Low</i> : 35  <i>High</i> 49  <i>Unit</i> %	Initial Entry
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**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**5.b Test:**

Date	Location	User	Value	Reason
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hematocrit_PX2	Initial Entry

**5.b Result:**

Date	Location	User	Value	Reason
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 48.4	Initial Entry

**5.b LNMT**

Date	Location	User	Value	Reason
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 35  <i>High</i> 49  <i>Unit</i> %	Initial Entry



5.c

Date	Location	User	Value	Reason
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined I</b> 3 <b>dentifier:</b> <b>Test::</b> Erythrocytes _PX3 <b>Result::</b> 5.02 <b>Not Done::</b> <b>Lab Normal Range</b> <i>Low</i> : 4.2  <i>High</i> 5.4  <i>Unit</i> 10 <sup>6</sup> /cu m m	Initial Entry

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**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**5.c Test:**

Date	Location	User	Value	Reason
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Erythrocytes_PX3	Initial Entry

**5.c Result:**

Date	Location	User	Value	Reason
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 5.02	Initial Entry

**5.c LNMT**

Date	Location	User	Value	Reason
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 4.2  <i>High</i> 5.4  <i>Unit</i> 10 <sup>6</sup> /cu mm	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Platelets_PX5 <b>Result::</b> 0.293 <b>Not Done::</b>	Initial Entry

			<b>Lab Normal Range:</b> <i>Low</i> 0.150  <i>High</i> 0.5  <i>Unit</i> 10 <sup>6</sup> /cu mm	
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**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

**5.d Test:**

Date	Location	User	Value	Reason
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Platelets_PX5	Initial Entry

**5.d Result:**

Date	Location	User	Value	Reason
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0.293	Initial Entry

**5.d LNMT**

Date	Location	User	Value	Reason
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Low</i> 0.150  <i>High</i> 0.5  <i>Unit</i> 10 <sup>6</sup> /cu mm	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Id 7 entifier:</b>	Initial Entry

			<b>Test::</b> Leukocytes_ PX7 <b>Result::</b> 16300 <b>Not Done::</b> <b>Lab Normal Range</b> <i>Low</i> : 4000  <i>High</i> 10000  <i>Unit</i> /uL	
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**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

**5.e Test:**

Date	Location	User	Value	Reason
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Leukocytes_PX7	Initial Entry

**5.e Result:**

Date	Location	User	Value	Reason
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 16300	Initial Entry

**5.e LNMT**

Date	Location	User	Value	Reason
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 4000  <i>High</i> 10000  <i>Unit</i> /uL	Initial Entry

**5.f**

Date	Location	User	Value	Reason
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<p>Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires</p>	<p>ACV0PFEINFP6000</p>	<p>auto calc (autocalc)</p>	<p><b>Data Entry:</b>  <b>Sponsor-Defined Identifier:</b> 608  <b>Test::</b> Neutrophils_  PX608  <b>Result::</b> 14197  <b>Not Done::</b>  <b>Lab Normal Range:</b> <i>Low</i>  e: 2500    <i>High</i>  7000    <i>Unit</i>  /uL</p>	<p>Initial Entry</p>
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<b>5.f Sponsor ID:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 608	Initial Entry
<b>5.f Test:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Neutrophils_PX608	Initial Entry
<b>5.f Result:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Nov-27-2020 03:44:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-26-2020 09:36:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The WBC differentials are in absolute values. They also are in "/cu mm" in the exam results, so we reported in microliter because the relation is 1/1.
Nov-26-2020 03:23:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6243760;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 14197	Initial Entry
<b>5.f LNMT</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Low 2500	Initial Entry

*High*  
7000

*Unit*  
/uL

5.g

Date	Location	User	Value	Reason
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 609 <b>Test::</b> Eosinophils_ PX609 <b>Result::</b> 82 <b>Not Done:</b> <b>Lab Normal Range:</b> <i>Low</i> 100  <i>High</i> 400  <i>Unit</i> /uL	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

<b>5.g Sponsor ID:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 609	Initial Entry
<b>5.g Test:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Eosinophils_PX609	Initial Entry
<b>5.g Result:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Nov-27-2020 03:44:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-26-2020 09:36:55 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The WBC differentials are in absolute values. They also are in "/cu mm" in the exam results, so we reported in microliter because the relation is 1/1.
Nov-26-2020 03:23:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6243853;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 82	Initial Entry
<b>5.g LNMT</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Low 100	Initial Entry



			<i>High</i> 400  <i>Unit</i> /uL	
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<b>5.h</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 612 <b>Test::</b> Monocytes_P X612 <b>Result::</b> 571 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 200  <i>High</i> 900  <i>Unit</i> /uL	Initial Entry

<b>5.h Sponsor ID:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 612	Initial Entry
<b>5.h Test:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Monocytes_PX612	Initial Entry
<b>5.h Result:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Nov-27-2020 03:45:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-26-2020 09:37:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The WBC differentials are in absolute values. They also are in "/cu mm" in the exam results, so we reported in microliter because the relation is 1/1.
Nov-26-2020 03:23:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6243847;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 571	Initial Entry

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Deleted, Frozen

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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

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5.h LNMT

Date	Location	User	Value	Reason
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 200  <i>High</i> 900  <i>Unit</i> /uL	Initial Entry

5.i

Date	Location	User	Value	Reason
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Basophils_P X610 <b>Result::</b> 0 <b>Not Done::</b> <b>Lab Normal Range</b> <i>Low</i> : 0  <i>High</i> 100  <i>Unit</i> /uL	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

<b>5.i Sponsor ID:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 610	Initial Entry
<b>5.i Test:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Basophils_PX610	Initial Entry
<b>5.i Result:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Nov-27-2020 03:45:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-26-2020 09:37:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The WBC differentials are in absolute values. They also are in "/cu mm" in the exam results, so we reported in microliter because the relation is 1/1.
Nov-26-2020 03:23:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6243854;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0	Initial Entry
<b>5.i LNMT</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Low 0	Initial Entry

			<i>High</i> 100  <i>Unit</i> /uL	
--	--	--	--	--

5.j				
Date	Location	User	Value	Reason
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 611 <b>Test::</b> Lymphocytes_PX611 <b>Result::</b> 1320 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 1000  <i>High</i> 1400  <i>Unit</i> /uL	Initial Entry

**5.j Sponsor ID:**

Date	Location	User	Value	Reason
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 611	Initial Entry

**5.j Test:**

Date	Location	User	Value	Reason
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Lymphocytes_PX611	Initial Entry

**5.j Result:**

Date	Location	User	Value	Reason
Nov-27-2020 03:46:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-26-2020 09:37:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The WBC differentials are in absolute values. They also are in "/cu mm" in the exam results, so we reported in microliter because the relation is 1/1.
Nov-26-2020 03:23:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6243846;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1320	Initial Entry

**5.j LNMT**

Date	Location	User	Value	Reason
Nov-25-2020 09:46:04 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Low 1000	Initial Entry

			<i>High</i> 1400	
			<i>Unit</i> /uL	

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Audit Trail

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

**Form Status:**

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> HEMATOLOGY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Feb-11-2021 07:17:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-09-2021 12:29:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Updated
Feb-09-2021 09:07:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Per completion guidelines, If multiple values were recorded on a single day, the most abnormal should be recorded, Please review the collection date 21Nov2020 and update as applicable. Else clarify.
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/21/2020	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLOOD	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.a

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 1 <b>Test::</b> Hemoglobin_PX1 <b>Result::</b> 15 <b>Not Done::</b> <b>Lab Normal Range</b> <i>Low</i> : 11.3  <i>High</i> 16.3  <i>Unit</i> g/dL	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hemoglobin_PX1	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 15	Initial Entry

5.a LNMT

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 11.3  <i>High</i> 16.3  <i>Unit</i> g/dL	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Hematocrit_ PX2 <b>Result::</b> 47.6 <b>Not Done::</b> <b>Lab Normal Range</b> <i>Low</i> : 35  <i>High</i> 49  <i>Unit</i> %	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.b Sponsor ID:

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 2	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Hematocrit_PX2	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 47.6	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <i>Low</i> 35  <i>High</i> 49  <i>Unit</i> %	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Sponsor-Defined I dentifier: 3	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

**Site No:** 1226

**Subject No:** 12261338

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

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

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

				<b>Test::</b>	Erythrocytes _PX3
				<b>Result::</b>	4.98
				<b>Not Done::</b>	
				<b>Lab Normal Range</b>	<i>Low</i>
				:	4.2
					<i>High</i>
					5.4
					<i>Unit</i>
					10 <sup>6</sup> /cu m
					m

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 3	Initial Entry

**5.c Test:**

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Erythrocytes_PX3	Initial Entry

**5.c Result:**

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 4.98	Initial Entry

**5.c LNMT**

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <i>Low</i> 4.2  <i>High</i> 5.4  <i>Unit</i> 10^6/cu mm	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> <b>Sponsor-Defined Identifier:</b> 5	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

**Site No:** 1226

**Subject No:** 12261338

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

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

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

				<b>Test::</b>	Platelets_P X5
				<b>Result::</b>	0.309
				<b>Not Done::</b>	
				<b>Lab Normal Range:</b>	<i>Low</i> 0.150
					<i>High</i> 0.5
					<i>Unit</i> 10^6/cu mm

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.d Sponsor ID:

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 5	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Platelets_PX5	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 0.309	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <i>Low</i> 0.150  <i>High</i> 0.5  <i>Unit</i> 10^6/cu mm	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Sponsor-Defined Identifier: 7	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

**Site No:** 1226

**Subject No:** 12261338

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

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

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

				<b>Test::</b>	Leukocytes_ PX7
				<b>Result::</b>	14700
				<b>Not Done::</b>	
				<b>Lab Normal Range</b>	<i>Low</i>
				:	4000
					<i>High</i>
					10000
					<i>Unit</i>
					/uL

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

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Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.e Sponsor ID:

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 7	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Leukocytes_PX7	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 14700	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <i>Low</i> 4000  <i>High</i> 10000  <i>Unit</i> /uL	Initial Entry

5.f

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Sponsor-Defined I 608 dentifier:	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

**Site No:** 1226

**Subject No:** 12261338

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

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

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

				<b>Test::</b>	Neutrophils_ PX608
				<b>Result::</b>	13715
				<b>Not Done::</b>	
				<b>Lab Normal Range:</b>	<i>Low</i>
				<b>e:</b>	2500
					<i>High</i>
					7000
					<i>Unit</i>
					/uL

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

**5.f Sponsor ID:**

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 608	Initial Entry

**5.f Test:**

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Neutrophils_PX608	Initial Entry

**5.f Result:**

Date	Location	User	Value	Reason
Nov-30-2020 03:09:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-26-2020 09:38:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The WBC differentials are in absolute values. They also are in "/cu mm" in the exam results, so we reported in microliter because the relation is 1/1.
Nov-26-2020 03:23:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6243844;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Nov-25-2020 09:51:25 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> :	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

City of Buenos Aires			13715	
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**5.f LNMT**

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 2500  <i>High</i> 7000  <i>Unit</i> /uL	Initial Entry

**5.g**

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 609 <b>Test::</b> Eosinophils_PX609 <b>Result::</b> 29 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> e: 100  <i>High</i> 400  <i>Unit</i> /uL	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

**5.g Sponsor ID:**

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 609	Initial Entry

**5.g Test:**

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Eosinophils_PX609	Initial Entry

**5.g Result:**

Date	Location	User	Value	Reason
Nov-30-2020 03:12:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-26-2020 09:39:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The WBC differentials are in absolute values. They also are in "/cu mm" in the exam results, so we reported in microliter because the relation is 1/1.
Nov-26-2020 03:23:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6243762;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Nov-25-2020 09:51:25 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> :	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

City of Buenos Aires			29	
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**5.g LNMT**

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 100  <i>High</i> 400  <i>Unit</i> /uL	Initial Entry

**5.h**

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 612 <b>Test::</b> Monocytes_P X612 <b>Result::</b> 221 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> e: 200  <i>High</i> 900  <i>Unit</i> /uL	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

**5.h Sponsor ID:**

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 612	Initial Entry

**5.h Test:**

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Monocytes_PX612	Initial Entry

**5.h Result:**

Date	Location	User	Value	Reason
Nov-30-2020 03:13:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-26-2020 09:39:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The WBC differentials are in absolute values. They also are in "/cu mm" in the exam results, so we reported in microliter because the relation is 1/1.
Nov-26-2020 03:23:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6243849;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Nov-25-2020 09:51:25 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> :	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

City of Buenos Aires			221	
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**5.h LNMT**

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 200  <i>High</i> 900  <i>Unit</i> /uL	Initial Entry

**5.i**

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Id 610</b> <b>entifier:</b> <b>Test::</b> Basophils_P X610 <b>Result::</b> 29 <b>Not Done::</b> <b>Lab Normal Range</b> <i>Low</i> : 0  <i>High</i> 100  <i>Unit</i> /uL	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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**5.i Sponsor ID:**

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 610	Initial Entry

**5.i Test:**

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Basophils_PX610	Initial Entry

**5.i Result:**

Date	Location	User	Value	Reason
Nov-30-2020 02:17:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-26-2020 09:39:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The WBC differentials are in absolute values. They also are in "/cu mm" in the exam results, so we reported in microliter because the relation is 1/1.
Nov-26-2020 03:23:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6243852;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : 29	Initial Entry
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5.i LNMT

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 0  <i>High</i> 100  <i>Unit</i> /uL	Initial Entry

5.j

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Lymphocytes_ PX611 <b>Result::</b> 706 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 1000  <i>High</i> 4000  <i>Unit</i> /uL	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

**5.j Sponsor ID:**

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 611	Initial Entry

**5.j Test:**

Date	Location	User	Value	Reason
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Lymphocytes_PX611	Initial Entry

**5.j Result:**

Date	Location	User	Value	Reason
Nov-27-2020 01:55:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-26-2020 09:39:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The WBC differentials are in absolute values. They also are in "/cu mm" in the exam results, so we reported in microliter because the relation is 1/1.
Nov-26-2020 03:23:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6243761;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Nov-25-2020 09:51:25 (UTC-03:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> :	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

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

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

City of Buenos Aires			706	
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**5.j LNMT**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Nov-25-2020 09:51:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 1000  <i>High</i> 4000  <i>Unit</i> /uL	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail  
on Nov/24/2020

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

**Form Status:**

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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Date	Location	User	Value	Reason
Nov-25-2020 09:36:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Nov/24/2020

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261338

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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**1. Date:**

Date	Location	User	Value	Reason
Nov-25-2020 09:36:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/24/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Nov-25-2020 09:36:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Systolic::</b> 12 7 <b>Diastolic::</b> 58 <b>Respiratory Rate in respir</b> <b>ations/minute:</b> 12 <b>Heart Rate in beats/minute</b> 74 :	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Nov-25-2020 09:36:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Systolic:**

Date	Location	User	Value	Reason
Nov-25-2020 09:36:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 127	Initial Entry

**2.a Diastolic:**

Date	Location	User	Value	Reason
Nov-30-2020 04:08:17 (UTC-03:00) City of	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History  
on Nov/24/2020**Form Version:** 21-Aug-2020 02:50**Form Status:** Data Complete, Frozen, Verified**Site No:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda**Subject No:** 12261338**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54

Buenos Aires		(b) (4), (b) (6)		
Nov-27-2020 10:01:57 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	PI evaluated that the value is not clinically significant.
Nov-26-2020 01:19:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Please confirm in query response if this value is clinically significant or not.
Nov-25-2020 12:14:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	confirm value as correct
Nov-25-2020 09:36:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Diastolic BP 58 is outside of Normal Range 60 - 90.
Nov-25-2020 09:36:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 58	Initial Entry

**2.a Respiratory Rate in respirations/minute:**

Date	Location	User	Value	Reason
Nov-25-2020 09:36:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 12	Initial Entry

**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Nov-25-2020 09:36:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 74	Initial Entry



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail  
on Nov/24/2020

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

**Form Status:**

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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Date	Location	User	Value	Reason
Nov-25-2020 09:39:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/24/2020

**Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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**1. Date:**

Date	Location	User	Value	Reason
Nov-25-2020 09:39:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/24/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Nov-25-2020 09:39:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Oxygen Saturation:</b> 99.0	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Nov-25-2020 09:39:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a SPO2 Pulse Oximetry %**

Date	Location	User	Value	Reason
Nov-25-2020 09:39:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 99.0	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Jan/13/2021

**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:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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**1. Date of Visit**

Date	Location	User	Value	Reason
Jan-13-2021 15:32:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/13/2021	Initial Entry

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

Date	Location	User	Value	Reason
Jan-13-2021 15:32:50 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COVID_A1	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Jan/13/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1226**Subject No:** 12261338**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:54[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-13-2021 17:10:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-13-2021 17:10:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-13-2021 17:10:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-13-2021 17:10:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-13-2021 17:10:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/13/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-13-2021 17:10:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP9945	Initial Entry

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled Visit on Jan/13/2021

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

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-19-2021 17:35:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_06
Jan-19-2021 10:19:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Data updated. The barcode of the subject 12261064 is BP994S.
Jan-19-2021 09:35:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6868759;The barcode BP9945 is recorded for two subjects 12261338 and 12261064, please review and update as appropriate.
Jan-13-2021 17:10:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> : BP9945	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Jan-13-2021 17:10:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> : <u>Sample ID</u> : BSF2DR	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Jan-13-2021 17:10:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry</u> : BSF2DR	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Jan/13/2021

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

**Site No:** 1226

**Subject No:** 12261338

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

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

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

**5.c**

Date	Location	User	Value	Reason
Jan-13-2021 17:10:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BSF2DS	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Jan-13-2021 17:10:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSF2DS	Initial Entry

**Header Text:** C4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Oct-08-2020 07:47:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/7/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-08-2020 07:47:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-08-2020 07:47:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261338

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:54

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-23-2021 10:07:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Jan/21/2021	Initial Entry



**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit  
Trail History

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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

Date	Location	User	Value	Reason
Jan-23-2021 10:08:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-23-2021 10:08:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-23-2021 10:08:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return f or Vaccination 3 Participant is:  eligible and NOT confirmed to have received only placeb o at Vaccination 1/2	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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Date	Location	User	Value	Reason
Sep-09-2020 13:15:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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Date	Location	User	Value	Reason
Sep-09-2020 13:16:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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Date	Location	User	Value	Reason
Sep-09-2020 13:17:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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Date	Location	User	Value	Reason
Oct-08-2020 07:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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Date	Location	User	Value	Reason
Oct-08-2020 07:34:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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Date	Location	User	Value	Reason
Nov-23-2020 15:22:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261338

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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**1. Category:**

Date	Location	User	Value	Reason
Sep-09-2020 13:15:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-09-2020 13:15:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Sep-09-2020 13:15:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Body pain	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Sep-09-2020 13:15:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/22/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Sep-09-2020 13:15:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Aug/23/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
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090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)



Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261338

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

Sep-09-2020 13:15:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Sep-09-2020 13:15:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-09-2020 13:15:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-09-2020 13:15:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-09-2020 13:15:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
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090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

Sep-09-2020 13:15:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry
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**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Sep-09-2020 13:15:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Sep-09-2020 13:15:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Sep-09-2020 13:15:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261338

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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**1. Category:**

Date	Location	User	Value	Reason
Sep-09-2020 13:16:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-09-2020 13:16:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Sep-09-2020 13:16:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Fever	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Sep-09-2020 13:16:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/22/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Sep-09-2020 13:16:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Aug/23/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261338

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Sep-09-2020 13:16:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Sep-09-2020 13:16:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-09-2020 13:16:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-09-2020 13:16:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-09-2020 13:16:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261338

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**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Sep-09-2020 13:16:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Sep-09-2020 13:16:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Sep-09-2020 13:16:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Sep-09-2020 13:16:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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**Site No:** 1226

**Subject No:** 12261338

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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**1. Category:**

Date	Location	User	Value	Reason
Sep-09-2020 13:17:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-09-2020 13:17:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Sep-09-2020 13:17:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Pain at injecton site	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Sep-09-2020 13:17:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/22/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Sep-09-2020 13:17:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Aug/23/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261338

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Sep-09-2020 13:17:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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
Sep-09-2020 13:17:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-09-2020 13:17:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-09-2020 13:17:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-09-2020 13:17:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Sep-09-2020 13:17:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Sep-09-2020 13:17:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Sep-09-2020 13:17:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Sep-09-2020 13:17:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)



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Site No: 1226

Subject No: 12261338

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

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**1. Category:**

Date	Location	User	Value	Reason
Oct-08-2020 07:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Oct-08-2020 07:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Oct-08-2020 07:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Pain at injection site	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Oct-08-2020 07:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/9/2020 18:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Oct-08-2020 07:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Sep/10/2020 UNK:UNK	Initial Entry

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Header Text: C4591001

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Site No: 1226

Subject No: 12261338

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-08-2020 07:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Oct-08-2020 07:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-08-2020 07:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-08-2020 07:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

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Oct-08-2020 07:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry
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**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Oct-08-2020 07:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Oct-08-2020 07:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Oct-08-2020 07:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Oct-08-2020 07:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

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Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

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**1. Category:**

Date	Location	User	Value	Reason
Oct-08-2020 07:34:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Oct-08-2020 07:34:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Oct-08-2020 07:34:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> chills	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Oct-08-2020 07:34:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/10/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Oct-08-2020 07:34:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Sep/10/2020 UNK:UNK	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

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Site No: 1226

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Form Status: Data Complete, Locked, Frozen

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-08-2020 07:34:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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
Oct-08-2020 07:34:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-08-2020 07:34:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-08-2020 07:34:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

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**Site No:** 1226

**Subject No:** 12261338

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

Oct-08-2020 07:34:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry
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**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Oct-08-2020 07:34:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Oct-08-2020 07:34:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Oct-08-2020 07:34:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Oct-08-2020 07:34:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

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Site No: 1226

Subject No: 12261338

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

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**1. Category:**

Date	Location	User	Value	Reason
Nov-23-2020 15:22:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Nov-23-2020 15:22:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Nov-23-2020 15:22:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Gastroenterocolitis	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Nov-23-2020 15:22:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/20/2020 22:00	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Dec-03-2020 13:44:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-03-2020 13:44:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:	Transcription Error

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1226**Subject No:** 12261338**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:54

			Nov/29/2020 UNK:UNK	
Dec-03-2020 13:44:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For Gastroenterocolitis End Date 29/Dec /2020, is a future date relative to when it was entered on 03/Dec/2020. Please correct.
Dec-03-2020 13:44:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Dec/29/2020 UNK:UNK	New Information
Nov-23-2020 15:22:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Nov-23-2020 15:22:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

**7. Is the adverse event serious?****If Yes, NOTIFY PFIZER IMMEDIATELY.**

**Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).**

Date	Location	User	Value	Reason
Nov-25-2020 06:52:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-23-2020 15:22:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Gastroenterocolitis: Response to "Is the adverse event



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**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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				serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-23-2020 15:22:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b> 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> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	Initial Entry

**8. Is this adverse event the result of a study Medication Error?**

*If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Nov-23-2020 15:22:56 (UTC-03:00) City of	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b> NO</p>	Initial Entry

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Buenos Aires		(b) (4), (b) (6)	
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-23-2020 15:22:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  If Other, specify:  Food poisoning	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-23-2020 15:22:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-23-2020 15:22:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-23-2020 15:22:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Dec-03-2020 13:45:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

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**Site No:** 1226

**Subject No:** 12261338

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

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**Generated Time (GMT):** 29-Mar-2021 13:54

Buenos Aires				
Dec-03-2020 13:45:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	New Information
Dec-03-2020 13:44:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Gastroenterocolitis: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Nov-23-2020 15:22:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERING/RESOLVING	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Nov-23-2020 15:22:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Nov-25-2020 06:52:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2020463228	Initial Entry

090177e196ae4052\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

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

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-01-2021 11:26:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/22/2021	Transcription Error
Jan-23-2021 10:08:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/21/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Jan-23-2021 10:08:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

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**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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**1. Subject Status**

Date	Location	User	Value	Reason
Oct-08-2020 07:47:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-21-2020 14:48:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-21-2020 14:44:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Oct-08-2020 07:47:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/7/2020	Initial Entry
Aug-21-2020 14:48:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/21/2020	Initial Entry
Aug-21-2020 14:44:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/21/2020	Initial Entry

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**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1226

**Subject No:** 12261338

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

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

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*1. Casebook Signature*

Date	Location	User	Value	Reason
Oct-21-2020 16:12:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry