

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION

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

**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:** 12262089

**Subject Initials:** ---

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

**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                        | 08 SEP 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:** 12262089

**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

[eCRF Audit Trail History](#)

**Informed Consent**

|    |              |   |
|----|--------------|---|
| 1. | Consent Was: | OBTAINED<br>Date Written Consent Obtained<br>Oct/6/2020 |
|----|--------------|---|

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1226

**Subject No:** 12262089

**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

[eCRF Audit Trail History](#)

**Demography**

|    |                                 |  |
|----|---------------------------------|--|
| 1. | Subject ID                      | [12262089]                                 |
| 2. | Birth Date:                     | (b) (6) 1975                               |
| 3. | Sex:                            | FEMALE                                     |
| 4. | Ethnicity:                      | HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN |
| 5. | Race: (Check X all that apply): | BLACK OR AFRICAN AMERICAN<br>WHITE         |
| 6. | Racial Designation:             |  |

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262089

**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/6/2020 |
| 2. | Erroneous Visit |            |

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262089

**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

**Form Comments**

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262089

**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

[eCRF Audit Trail History](#)

**Disposition - Screening**

|    |  |            |
|----|--|------------|
| 1. | Date of Completion/Discontinuation/Death | Oct/6/2020 |
| 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:** 12262089

**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

[eCRF Audit Trail History](#)

**Medical History Details**

|     |  |                                 |
|-----|--|---------------------------------|
| 1.a | Line/MH Number:  | [1]                             |
|     | Disease/Syndrome/Surgery<br>/Non-Drug Allergies/Drug<br>Allergies: | [Bilateral tubal ligation]      |
|     | Start Date:  | UNK/UNK/2006                    |
|     | Ongoing:   | NO<br>End Date:<br>UNK/UNK/2006 |

**Header Text:** C4591001

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

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1226

**Subject No:** 12262089

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

**Form:** HIV STATUS

**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](#)

**HIV Status**

|    |   |   |
|----|---|---|
| 1. | Select appropriate response - What is the subject HIV status? | The subject is NOT known to be HIV POSITIVE |
|----|---|---|



**Header Text:** C4591001

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

**Form Version:** 15-Sep-2020 21:56

**Site No:** 1226

**Subject No:** 12262089

**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:            | Oct/6/2020 |
| 2. | Weight:          | [56.0]     |
| 3. | Unit:            | kg         |
| 4. | Height:          | [161.0]    |
| 5. | Unit:            | cm         |
| 6. | Body Mass Index: | [21.6]     |

**Vital Signs Details**

|     |                       |          |
|-----|-----------------------|----------|
| 7.a | Record Identifier:    | 1        |
|     | Temperature:          | [36.5]   |
|     | Unit:                 | C        |
|     | Temperature Location: | FOREHEAD |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262089

**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:                      | Oct/6/2020   |
| 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:** 12262089

**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 :  | Oct/6/2020 |
| 2. | Randomization Number: | [103777]   |
| 3. | Randomization Group:  | [ ]        |

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262089

**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<br>Date of Collection:<br>Oct/6/2020 |
| 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 | [BPWZ3D] |
| 5.b | Sample ID | [BRVC5K] |
| 5.c | Sample ID | [BRVC5J] |

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**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262089

**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<br>Date of Collection:<br>Oct/6/2020 |
| 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 | [BPVZ36] |
|-----|-----------|----------|

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262089

**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:   | Oct/6/2020 11:40                          |
| 5.  | Anatomical Location:  | DELTOID MUSCLE                            |
| 6.  | Body Side:  | LEFT                                      |
| 7.  | Route:  | INTRAMUSCULAR                             |
| 8.  | Actual Dose:  | [ ]                                       |
| 9.  | Unit:   |   |
| 10. | Timeframe Subject Was Observed  | THE PROTOCOL SPECIFIED OBSERVATION PERIOD |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES                                       |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262089

**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 |
|----|---|--|

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1226

**Subject No:** 12262089

**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   | Nov/6/2020 |
| 2. | Erroneous Visit |            |



**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1226

**Subject No:** 12262089

**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: | Nov/6/2020 |
|----|-------|------------|

**Vital Signs Details**

|     |                       |          |
|-----|-----------------------|----------|
| 2.a | Record Identifier:    | 1        |
|     | Temperature:          | [36.5]   |
|     | Unit:                 | C        |
|     | Temperature Location: | FOREHEAD |

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1226

**Subject No:** 12262089

**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:                      | Nov/6/2020   |
| 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:** 12262089

**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<br>Date of Collection:<br>Nov/6/2020 |
| 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 | [BR690Z] |
|-----|-----------|----------|

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1226

**Subject No:** 12262089

**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:   | Nov/6/2020 10:16                          |
| 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                                       |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262089

**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   | Dec/10/2020 |
| 2. | Erroneous Visit |             |

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262089

**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<br>Date of Collection:<br>Dec/10/2020 |
| 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 | [BRGTGH] |
| 5.b | Sample ID | [BSF1YT] |
| 5.c | Sample ID | [BSF1YV] |

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**Header Text:** C4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1226

**Subject No:** 12262089

**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:** V4\_MONTH6\_L

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

**Site No:** 1226

**Subject No:** 12262089

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

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)



**Header Text:** C4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1226

**Subject No:** 12262089

**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:** 12262089

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

**Header Text:** C4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1226

**Subject No:** 12262089

**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:** 12262089

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET  
on Oct/09/2020

**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:** 12262089

**Subject Initials:** ---

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

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

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**Date of Visit**

|    |                 |            |
|----|-----------------|------------|
| 1. | Date of Visit   | Oct/9/2020 |
| 2. | Erroneous Visit |            |

**COVID-19 Illness Visit**

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19  
on Oct/09/2020

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

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**Signs and Symptoms**

|    |                                |   |
|----|--------------------------------|---|
| 1. | Date of Assessment:            | Oct/9/2020  |
| 2. | Date of First Symptom Started: | Oct/7/2020  |
| 3. | Symptoms Ongoing?              | NO<br>Date of Last Symptom Resolved:<br>Oct/11/2020 |

**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? | YES                                  |
| 4.h | Symptoms:            | DIARRHEA                             |
|     | Was symptom present? | NO                                   |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Oct/09/2020

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

|     |                      |          |
|-----|----------------------|----------|
| 4.i | Symptoms:            | VOMITING |
|     | Was symptom present? | NO       |

**Symptoms - Other**

|     |                        |            |
|-----|------------------------|------------|
| 5.a | Symptoms - Other Text: | [headache] |
|-----|------------------------|------------|

**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:** 12262089

**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 Done           | Not Done      | Not Done                     | Not Done                   | Not Done    | <a href="#">Repeating Pages</a> |



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN  
on Oct/09/2020

**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:** 12262089

**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 Done<br>_____<br>//  | <a href="#">Comments</a> |
| 2. | Specimen Type:                | Not Done<br>_____        | <a href="#">Comments</a> |
| 3. | Specimen Collection Location: | Not Done<br>_____        | <a href="#">Comments</a> |
| 4. | Assay Code and Description:   | Not Done<br>_____        | <a href="#">Comments</a> |
| 5. | Device Type:                  | Not Done<br>_____        | <a href="#">Comments</a> |
| 6. | Trade Name:                   | Not Done<br>_____        | <a href="#">Comments</a> |
| 7. | Test Result:                  | Not Done<br>_____        | <a href="#">Comments</a> |
| 8. | Comments/Findings/Details:    | Not Done<br>_____<br>[ ] | <a href="#">Comments</a> |
| 9. | Trade Name Other, Specify:    | Not Done<br>_____<br>[ ] | <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 Oct/09/2020

**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:** 12262089

**Subject Initials:** ---

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

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

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**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
on Oct/09/2020

**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:** 12262089

**Subject Initials:** ---

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

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

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**Electronic Sample Tracking**

|    |  |  |
|----|--|--|
| 1. | Data Origin  | SITE                                     |
| 2. | Sample Type  | NASAL_SWAB                               |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Oct/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 | [BPWZF1] |
|-----|-----------|----------|

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION  
on Oct/09/2020

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

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**Health Care Utilization**

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

**Health Care Utilization Other**

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

**Health Care Utilization**

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

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**Header Text:** C4591001

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

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

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

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT  
on Oct/09/2020

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
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**Subject No:** 12262089

**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?             | Not Applicable<br>_____<br>[ ] | <a href="#">Comments</a> |
| 2. | Concomitant Non-drug Treatment Pre-specified: | Not Applicable<br>_____        | <a href="#">Comments</a> |
| 3. | Treatment:                                    | Not Applicable<br>_____        | <a href="#">Comments</a> |
| 4. | Treatment:                                    | Not Applicable<br>_____<br>[ ] | <a href="#">Comments</a> |
| 5. | Start Date:                                   | Not Applicable<br>_____<br>//  | <a href="#">Comments</a> |
| 6. | Ongoing?                                      | Not Applicable<br>_____        | <a href="#">Comments</a> |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS  
on Oct/09/2020

**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:** 12262089

**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:                              | POTENTIAL COVID-19 ILLNESS |
| 2. | Was a diagnosis obtained for Potential COVID-19 Illness? | NO                         |
| 3. | Toxicity Grade:  | 1                          |

**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:** 12262089

**Subject Initials:** ---

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

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

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



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE  
on Oct/09/2020

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

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

**Site No:** 1226

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

**Subject No:** 12262089

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

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 15-Sep-2020 21:51

Site No: 1226

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

Subject No: 12262089

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. | Not Done              | Not Done    | Not Done         | Not Done      | <b>Sponsor-Defined Identifier</b> | <b>Test:</b> | <b>Result:</b> | <a href="#">Repeating Pages</a> |
|    |                       |             |                  |               | Not Done                          | Not Done     | Not Done       |                                 |
|    |                       |             |                  |               | Not Done                          | Not Done     | Not Done       |                                 |
|    |                       |             |                  |               | Not Done                          | Not Done     | Not Done       |                                 |
|    |                       |             |                  |               | Not Done                          | Not Done     | Not Done       |                                 |
|    |                       |             |                  |               | Not Done                          | Not Done     | Not Done       |                                 |
|    |                       |             |                  |               | Not Done                          | Not Done     | Not Done       |                                 |
|    |                       |             |                  |               | Not Done                          | Not Done     | Not Done       |                                 |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Oct/09/2020

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

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**Lab Chemistry Details**

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

**Lab Result**

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

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Oct/09/2020

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

|     |             |  |                          |
|-----|-------------|--|--------------------------|
| 5.b | Sponsor ID: | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Test:       | Alanine Aminotransferase_PX30                          |                          |
|     | Result:     | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Not Done:   | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | LNMT        | Not Done<br>_____<br>Low<br>[ ]<br>High<br>[ ]<br>Unit | <a href="#">Comments</a> |
| 5.c | Sponsor ID: | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Test:       | Aspartate Aminotransferase_PX28                        |                          |
|     | Result:     | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Not Done:   | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | LNMT        | Not Done<br>_____<br>Low<br>[ ]<br>High<br>[ ]<br>Unit | <a href="#">Comments</a> |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Oct/09/2020

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

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

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Oct/09/2020

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

|     |             |  |                          |
|-----|-------------|--|--------------------------|
| 5.f | Sponsor ID: | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Test:       | Blood Urea Nitrogen_PX47                               |                          |
|     | Result:     | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Not Done:   | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | LNMT        | Not Done<br>_____<br>Low<br>[ ]<br>High<br>[ ]<br>Unit | <a href="#">Comments</a> |
| 5.g | Sponsor ID: | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Test:       | Creatinine_PX48  |                          |
|     | Result:     | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Not Done:   | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | LNMT        | Not Done<br>_____<br>Low<br>[ ]<br>High<br>[ ]<br>Unit | <a href="#">Comments</a> |

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 15-Sep-2020 21:55

Site No: 1226

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

Subject No: 12262089

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. | Not Done              | Not Done              | Not Done         | Not Done      | <b>Sponsor-Defined Identifier</b> | <b>Test:</b> | <b>Result :</b> | <a href="#">Repeating Pages</a> |
|    |                       |                       |                  |               | Not Done                          | Not Done     | Not Done        |                                 |
|    |                       |                       |                  |               | Not Done                          | Not Done     | Not Done        |                                 |
|    |                       |                       |                  |               | Not Done                          | Not Done     | Not Done        |                                 |
|    |                       |                       |                  |               | Not Done                          | Not Done     | Not Done        |                                 |
|    |                       |                       |                  |               | Not Done                          | Not Done     | Not Done        |                                 |
|    |                       |                       |                  |               | Not Done                          | Not Done     | Not Done        |                                 |
|    |                       |                       |                  |               | Not Done                          | Not Done     | Not Done        |                                 |
|    |                       |                       |                  |               | Not Done                          | Not Done     | Not Done        |                                 |
|    |                       |                       |                  |               | Not Done                          | Not Done     | Not Done        |                                 |
|    |                       |                       |                  |               | Not Done                          | Not Done     | Not Done        |                                 |

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Oct/09/2020

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

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**Laboratory Data Hematology**

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

**Lab Result**

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

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Oct/09/2020

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

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

**Site No:** 1226

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|     |             |  |                          |
|-----|-------------|--|--------------------------|
| 5.b | Sponsor ID: | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Test:       | Hematocrit_PX2   |                          |
|     | Result:     | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Not Done:   | Not Done<br>_____                                      | <a href="#">Comments</a> |
|     | LNMT        | Not Done<br>_____<br>Low<br>[ ]<br>High<br>[ ]<br>Unit | <a href="#">Comments</a> |
| 5.c | Sponsor ID: | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Test:       | Erythrocytes_PX3                                       |                          |
|     | Result:     | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Not Done:   | Not Done<br>_____                                      | <a href="#">Comments</a> |
|     | LNMT        | Not Done<br>_____<br>Low<br>[ ]<br>High<br>[ ]<br>Unit | <a href="#">Comments</a> |

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Oct/09/2020

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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|     |             |  |                          |
|-----|-------------|--|--------------------------|
| 5.d | Sponsor ID: | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Test:       | Platelets_PX5  |                          |
|     | Result:     | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Not Done:   | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | LNMT        | Not Done<br>_____<br>Low<br>[ ]<br>High<br>[ ]<br>Unit | <a href="#">Comments</a> |
| 5.e | Sponsor ID: | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Test:       | Leukocytes_PX7   |                          |
|     | Result:     | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Not Done:   | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | LNMT        | Not Done<br>_____<br>Low<br>[ ]<br>High<br>[ ]<br>Unit | <a href="#">Comments</a> |

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**Header Text:** C4591001

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

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

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

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Oct/09/2020

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

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

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**Header Text:** C4591001

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

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

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**Header Text:** C4591001

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

**Form:** VITAL SIGNS - COVID

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

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

| #  | Date:      | Vital Signs Details       |                  |                   | Form Instance                   |
|----|------------|---------------------------|------------------|-------------------|---------------------------------|
| 1. | Oct/9/2020 | <b>Record Identifier:</b> | <b>Systolic:</b> | <b>Diastolic:</b> | <a href="#">Repeating Pages</a> |
|    |            | 1                         | 128              | 82                |                                 |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID  
on Oct/09/2020

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
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**Subject No:** 12262089

**Subject Initials:** ---

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

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**Vital Signs**

|    |       |            |
|----|-------|------------|
| 1. | Date: | Oct/9/2020 |
|----|-------|------------|

**Vital Signs Details**

|     |   |       |
|-----|---|-------|
| 2.a | Record Identifier:                          | 1     |
|     | Systolic:                                   | [128] |
|     | Diastolic:                                  | [82]  |
|     | Respiratory Rate in<br>respirations/minute: | [16]  |
|     | Heart Rate in beats/minute:                 | [56]  |

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**Header Text:** C4591001

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

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

| #                  | Date:             | Vital Signs Details  |                    | Form Instance     |   |      |  |                                 |
|--------------------|-------------------|--|--------------------|-------------------|---|------|--|---------------------------------|
| 1.                 | Oct/9/2020        | <table border="1"><thead><tr><th>Record Identifier:</th><th>Oxygen Saturation</th></tr></thead><tbody><tr><td>1</td><td>95.0</td></tr></tbody></table> | Record Identifier: | Oxygen Saturation | 1 | 95.0 |  | <a href="#">Repeating Pages</a> |
| Record Identifier: | Oxygen Saturation |  |                    |                   |   |      |  |                                 |
| 1                  | 95.0              |  |                    |                   |   |      |  |                                 |



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
on Oct/09/2020

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
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**Subject No:** 12262089

**Subject Initials:** ---

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**Vital Signs**

|    |       |            |
|----|-------|------------|
| 1. | Date: | Oct/9/2020 |
|----|-------|------------|

**Vital Signs Details**

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

**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:** 12262089

**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. | Not Applicable          | Not Applicable            | Not Applicable                    | <a href="#">Repeating Pages</a> |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS  
on Oct/09/2020

**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  
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**Subject No:** 12262089

**Subject Initials:** ---

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

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

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

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

**Site No:** 1226

**Subject No:** 12262089

**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. | Not Applicable             | Not Applicable          | Not Applicable                        | Not Applicable     | Not Applicable | <a href="#">Repeating Pages</a> |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS  
on Oct/09/2020

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

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

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
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**Concomitant Medications**

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

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**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. | Not Done           | Not Done               | Not Done       | Not Done           | <a href="#">Repeating Pages</a> |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** IMAGING  
on Oct/09/2020

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

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

**Site No:** 1226

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

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET  
on Dec/28/2020

**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  
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**Subject No:** 12262089

**Subject Initials:** ---

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

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

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**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Dec/28/2020 |
| 2. | Erroneous Visit |             |

**COVID-19 Illness Visit**

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



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19  
on Dec/28/2020

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

**Form Status:** Data Complete

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
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**Subject No:** 12262089

**Subject Initials:** ---

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

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

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**Signs and Symptoms**

|    |                                |   |
|----|--------------------------------|---|
| 1. | Date of Assessment:            | Dec/28/2020   |
| 2. | Date of First Symptom Started: | Dec/25/2020   |
| 3. | Symptoms Ongoing?              | NO<br>Date of Last Symptom Resolved:<br>Dec/30/2020 |

**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? | YES                                  |
| 4.h | Symptoms:            | DIARRHEA                             |
|     | Was symptom present? | NO                                   |

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19  
on Dec/28/2020

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

**Form Status:** Data Complete

**Site No:** 1226

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|     |                      |          |
|-----|----------------------|----------|
| 4.i | Symptoms:            | VOMITING |
|     | Was symptom present? | NO       |

**Symptoms - Other**

|     |                        |          |
|-----|------------------------|----------|
| 5.a | Symptoms - Other Text: | [Coryza] |
|-----|------------------------|----------|

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**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:** 12262089

**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 Done           | Not Done      | Not Done                     | Not Done                   | Not Done    | <a href="#">Repeating Pages</a> |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN  
on Dec/28/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1226

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

**Subject No:** 12262089

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

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Dec/28/2020

**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:** 12262089

**Subject Initials:** ---

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

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

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**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
on Dec/28/2020

**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:** 12262089

**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<br>Date of Collection:<br>Dec/28/2020 |
| 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 | [BP990J] |
|-----|-----------|----------|

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION  
on Dec/28/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1226

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

**Subject No:** 12262089

**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:     | NO                     |
| 1.c | Physician or Healthcare Professional: | PRIMARY CARE PHYSICIAN |
|     | Occurrence of Visits or Contacts:     | NO                     |
| 1.d | Physician or Healthcare Professional: | URGENT CARE            |
|     | Occurrence of Visits or Contacts:     | NO                     |
| 1.e | Physician or Healthcare Professional: | TELEPHONE CONSULTATION |
|     | Occurrence of Visits or Contacts:     | NO                     |
| 1.f | Physician or Healthcare Professional: | OTHER                  |
|     | Occurrence of Visits or Contacts:     | NO                     |

**Health Care Utilization Other**

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

**Health Care Utilization**

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

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** RESPIRATORY TREATMENT

**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:** 12262089

**Subject Initials:** ---

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

**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 2 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT  
on Dec/28/2020

**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:** 12262089

**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<br>Pre-specified: |     |
| 3. | Treatment:                                       |     |
| 4. | Treatment:                                       | [ ] |
| 5. | Start Date:                                      | //  |
| 6. | Ongoing?   |     |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** ILLNESS DETAILS  
on Dec/28/2020

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

**Form Status:** Data Complete

**Site No:** 1226

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

**Subject No:** 12262089

**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:                              | POTENTIAL COVID-19 ILLNESS |
| 2. | Was a diagnosis obtained for Potential COVID-19 Illness? | NO                         |
| 3. | Toxicity Grade:  | 1                          |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**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:** 12262089

**Subject Initials:** ---

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

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

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE  
on Dec/28/2020

**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:** 12262089

**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 2

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

**Site No:** 1226

**Subject No:** 12262089

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

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

**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 | Collection Date: | Specimen Type | Lab Result                 |       |         | Form Instance                   |
|----|-----------------------|-------------|------------------|---------------|----------------------------|-------|---------|---------------------------------|
| 1. |                       |             |                  |               | Sponsor-Defined Identifier | Test: | Result: | <a href="#">Repeating Pages</a> |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Dec/28/2020

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

**Form Status:** Not Started

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

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**Lab Chemistry Details**

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

**Lab Result**

|    |             |                                   |
|----|-------------|-----------------------------------|
| 5. | Sponsor ID: | [ ]                               |
|    | Test:       |                                   |
|    | Result:     | [ ]                               |
|    | Not Done:   |                                   |
|    | LNMT        | Low<br>[ ]<br>High<br>[ ]<br>Unit |

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

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

**Site No:** 1226

**Subject No:** 12262089

**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 (DE RIVED) | Collection Date: | Specimen Type | Lab Result                 |       |         | Form Instance                   |
|----|-----------------------|------------------------|------------------|---------------|----------------------------|-------|---------|---------------------------------|
| 1. |                       |                        |                  |               | Sponsor-Defined Identifier | Test: | Result: | <a href="#">Repeating Pages</a> |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Dec/28/2020

**Form Version:** 15-Sep-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:** 12262089

**Subject Initials:** ---

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

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

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**Laboratory Data Hematology**

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

**Lab Result**

|    |             |                                   |
|----|-------------|-----------------------------------|
| 5. | Sponsor ID: | [ ]                               |
|    | Test:       |                                   |
|    | Result:     | [ ]                               |
|    | Not Done:   |                                   |
|    | LNMT        | Low<br>[ ]<br>High<br>[ ]<br>Unit |

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** VITAL SIGNS - COVID

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

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

| #  | Date:       | Vital Signs Details       |                  |                   | Form Instance                   |
|----|-------------|---------------------------|------------------|-------------------|---------------------------------|
| 1. | Dec/28/2020 | <b>Record Identifier:</b> | <b>Systolic:</b> | <b>Diastolic:</b> | <a href="#">Repeating Pages</a> |
|    |             | 1                         | 131              | 77                |                                 |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** VITAL SIGNS - COVID  
on Dec/28/2020

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

**Form Status:** Data Complete

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
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**Subject No:** 12262089

**Subject Initials:** ---

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

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

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**Vital Signs**

|    |       |             |
|----|-------|-------------|
| 1. | Date: | Dec/28/2020 |
|----|-------|-------------|

**Vital Signs Details**

|     |  |       |
|-----|--|-------|
| 2.a | Record Identifier:                       | 1     |
|     | Systolic:                                | [131] |
|     | Diastolic:                               | [77]  |
|     | Respiratory Rate in respirations/minute: | [16]  |
|     | Heart Rate in beats/minute:              | [76]  |

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

| #  | Date:       | Vital Signs Details       |                          | Form Instance                   |
|----|-------------|---------------------------|--------------------------|---------------------------------|
| 1. | Dec/28/2020 | <b>Record Identifier:</b> | <b>Oxygen Saturation</b> | <a href="#">Repeating Pages</a> |
|    |             | 1                         | 99.0                     |                                 |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
on Dec/28/2020

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

**Form Status:** Data Complete

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
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**Subject No:** 12262089

**Subject Initials:** ---

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

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

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**Vital Signs**

|    |       |             |
|----|-------|-------------|
| 1. | Date: | Dec/28/2020 |
|----|-------|-------------|

**Vital Signs Details**

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**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:** 12262089

**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> |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS  
on Dec/28/2020

**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:** 12262089

**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 2

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

**Site No:** 1226

**Subject No:** 12262089

**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 2 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS  
on Dec/28/2020

**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:** 12262089

**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<br>Pre-specified:   |     |
| 4. | Medication:<br><br>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 2

**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:** 12262089

**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 2 - Unscheduled Visit **Form:** IMAGING  
on Dec/28/2020

**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:** 12262089

**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 Nov/06/2020

**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:** 12262089

**Subject Initials:** ---

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

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

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**Date of Visit**

|    |                 |            |
|----|-----------------|------------|
| 1. | Date of Visit   | Nov/6/2020 |
| 2. | Erroneous Visit |            |

**COVID-19 Illness Visit**

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled Visit on Nov/06/2020 **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:** 12262089

**Subject Initials:** ---

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

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

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**Electronic Sample Tracking**

|    |  |  |
|----|--|--|
| 1. | Data Origin  | SITE                                     |
| 2. | Sample Type  | SERUM                                    |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Nov/6/2020 |
| 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 | [BR691S] |
| 5.b | Sample ID | [BS2XCB] |
| 5.c | Sample ID | [BS2XCC] |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 2 - Unscheduled  
Visit on Jan/27/2021

**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:** 12262089

**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/27/2021 |
| 2. | Erroneous Visit |             |

**COVID-19 Illness Visit**

|    |                         |          |
|----|-------------------------|----------|
| 3. | COVID-19 Illness Visit: | COVID_B1 |
|----|-------------------------|----------|

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 2 - Unscheduled  
Visit on Jan/27/2021

**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:** 12262089

**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<br>Date of Collection:<br>Jan/27/2021 |
| 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 | [BRH0HD] |
| 5.b | Sample ID | [BSF3ZM] |
| 5.c | Sample ID | [BSF3ZN] |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**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:** 12262089

**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:** 12262089

**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 - New Unscheduled Visit

**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:** 12262089

**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 - 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:** 12262089

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

**Site No:** 1226

**Subject No:** 12262089

**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 : | Dec/10/2020 |
| 2. | Phase of Disposition:                      | VACCINATION |
| 3. | Status:                                    | COMPLETED   |
| 4. | Specify Status:                            | [ ]         |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**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:** 12262089

**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:** 12262089

**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:** 12262089

**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:   |     |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (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:** 12262089

**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? |     |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

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

**Form Status:** Not Started

**Site No:** 1226

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

**Subject No:** 12262089

**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:** 12262089

**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:** 12262089

**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:** 12262089

**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:** 12262089

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

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262089

**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:** Follow-Up - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262089

**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:** 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:** 12262089

**Subject Initials:** ---

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

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

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**Date of Visit**

|    |                 |            |
|----|-----------------|------------|
| 1. | Date of Visit   | Feb/8/2021 |
| 2. | Erroneous Visit |            |

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262089

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

**Form:** FURTHER VACCINATION CONFIRMATION

**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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**Further Vaccination Confirmation**

|    |   |  |
|----|---|--|
| 1. | Select appropriate response - Is participant willing to return for Vaccination 3? | Participant is willing to return for Vaccination 3<br>Participant is:<br>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: 12262089

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             | Urinary tract infection | Oct/18/2020 06:00 | NO<br>End Date Time:<br><br>Oct/22/2020 UNK:UNK | <a href="#">Repeating Pages</a> |
| 2. | ADVERSE EVENT | 2             | Pain at injection site  | Nov/6/2020 21:00  | NO<br>End Date Time:<br><br>Nov/7/2020 UNK:UNK  | <a href="#">Repeating Pages</a> |
| 3. | ADVERSE EVENT | 3             | Malaise                 | Nov/6/2020 21:00  | NO<br>End Date Time:<br><br>Nov/6/2020 UNK:UNK  | <a href="#">Repeating Pages</a> |
| 4. | ADVERSE EVENT | 4             | Chills                  | Nov/6/2020 21:00  | NO<br>End Date Time:<br><br>Nov/6/2020 UNK:UNK  | <a href="#">Repeating Pages</a> |
| 5. | ADVERSE EVENT | 5             | Muscle pain             | Nov/6/2020 21:00  | NO<br>End Date Time:<br><br>Nov/6/2020 UNK:UNK  | <a href="#">Repeating Pages</a> |
| 6. | ADVERSE EVENT | 6             | Nausea                  | Nov/6/2020 21:00  | NO<br>End Date Time:<br><br>Nov/6/2020 UNK:UNK  | <a href="#">Repeating Pages</a> |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262089

**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:** ---

**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:<br>(If possible specify diagnosis, not individual symptoms)  | [Urinary tract infection]   |
| 4. | Start Date Time:  | Oct/18/2020 06:00   |
| 5. | Is the adverse event still ongoing?   | NO<br>End Date Time:<br>Oct/22/2020 UNK:UNK   |
| 6. | Toxicity Grade:   | 3   |
| 7. | Is the adverse event serious?<br><br>If Yes, NOTIFY PFIZER IMMEDIATELY.<br><br>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<br><br>Is this serious event associated with congenital anomaly or birth defect?<br>NO<br><br>Did this serious event result in death?<br>NO<br><br>Did this serious event require or prolong hospitalization?<br>YES<br><br>Did this serious event result in persistent or significant disability/incapacity?<br>NO<br><br>Is this serious event life threatening?<br>NO<br><br>Other medically important serious event<br>NO |
| 8. | Is this adverse event the result of a study Medication Error?<br>If Yes, record the type of medication error on the Medication Error Log.   | NO  |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262089

**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:** ---

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

|     |  |  |
|-----|--|--|
| 9.  | Is this event related to study treatment:                                  | NOT RELATED<br>If Not Related to study treatment(s), this event is due to:<br>OTHER<br>If Other, specify:<br>[urinary infection] |
| 10. | Latest Action Taken with Study Treatment:                                  | NOT APPLICABLE   |
| 11. | Was a Concomitant Medication given?  | YES  |
| 12. | Was a Non-Drug Treatment given?  | NO   |
| 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:<br>For Pfizer Use Only                       | [2020437602]   |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262089

**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:  | [2]  |
| 3.  | Adverse Event:<br>(If possible specify diagnosis, not individual symptoms)  | [Pain at injection site]                   |
| 4.  | Start Date Time:  | Nov/6/2020 21:00                           |
| 5.  | Is the adverse event still ongoing?   | NO<br>End Date Time:<br>Nov/7/2020 UNK:UNK |
| 6.  | Toxicity Grade:   | 1  |
| 7.  | Is the adverse event serious?<br><br>If Yes, NOTIFY PFIZER IMMEDIATELY.<br><br>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?<br>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                             |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262089

**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:<br>For Pfizer Use Only                       | [ ]                |

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262089

**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:<br>(If possible specify diagnosis, not individual symptoms)  | [Malaise]                                  |
| 4.  | Start Date Time:  | Nov/6/2020 21:00                           |
| 5.  | Is the adverse event still ongoing?   | NO<br>End Date Time:<br>Nov/6/2020 UNK:UNK |
| 6.  | Toxicity Grade:   | 1  |
| 7.  | Is the adverse event serious?<br><br>If Yes, NOTIFY PFIZER IMMEDIATELY.<br><br>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?<br>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                             |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262089

**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:<br>For Pfizer Use Only                       | [ ]                |

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262089

**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:<br>(If possible specify diagnosis, not individual symptoms)  | [Chills]                                   |
| 4.  | Start Date Time:  | Nov/6/2020 21:00                           |
| 5.  | Is the adverse event still ongoing?   | NO<br>End Date Time:<br>Nov/6/2020 UNK:UNK |
| 6.  | Toxicity Grade:   | 1  |
| 7.  | Is the adverse event serious?<br><br>If Yes, NOTIFY PFIZER IMMEDIATELY.<br><br>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?<br>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                             |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262089

**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:<br>For Pfizer Use Only                       | [ ]                |

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262089

**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:  | [5]  |
| 3.  | Adverse Event:<br>(If possible specify diagnosis, not individual symptoms)  | [Muscle pain]                              |
| 4.  | Start Date Time:  | Nov/6/2020 21:00                           |
| 5.  | Is the adverse event still ongoing?   | NO<br>End Date Time:<br>Nov/6/2020 UNK:UNK |
| 6.  | Toxicity Grade:   | 1  |
| 7.  | Is the adverse event serious?<br><br>If Yes, NOTIFY PFIZER IMMEDIATELY.<br><br>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?<br>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                             |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262089

**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:<br>For Pfizer Use Only                       | [ ]                |

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262089

**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:  | [6]  |
| 3.  | Adverse Event:<br>(If possible specify diagnosis, not individual symptoms)  | [Nausea]                                   |
| 4.  | Start Date Time:  | Nov/6/2020 21:00                           |
| 5.  | Is the adverse event still ongoing?   | NO<br>End Date Time:<br>Nov/6/2020 UNK:UNK |
| 6.  | Toxicity Grade:   | 1  |
| 7.  | Is the adverse event serious?<br><br>If Yes, NOTIFY PFIZER IMMEDIATELY.<br><br>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?<br>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:** 12262089

**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:<br>For Pfizer Use Only                       | [ ]                |

**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:** 12262089

**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:** 12262089

**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:** ---

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

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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                             | [ ] |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**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:** 12262089

**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  
Servicos Medicos Ltda

**Subject No:** 12262089

**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<br>Pre-specified:   |     |
| 4. | Medication:<br><br>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:   | //  |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**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:** 12262089

**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:** 12262089

**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<br>Pre-specified:   |     |
| 4.  | Medication:<br><br>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?  |     |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**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:** 12262089

**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:** 12262089

**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:** 12262089

**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:** 12262089

**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 Servicos Medicos Ltda

**Subject No:** 12262089

**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:** 12262089

**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? |  |
|----|--|--|

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262089

**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

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**Treatment Unblinded**

|    |                                |   |
|----|--------------------------------|---|
| 1. | Date Treatment Unblinded :     | Feb/9/2021                                    |
| 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:** 12262089

**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 : | // |
|----|------------------------------|----|

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262089

**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: | // |
|----|---|----|

**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:** 12262089

**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

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**Subject Status**

|    |                     |             |
|----|---------------------|-------------|
| 1. | Subject Status      | FOLLOW-UP   |
| 2. | Subject Status Date | Dec/10/2020 |

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262089

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

**Form:** CASEBOOK SIGNATURE FORM

**Form Status:** Data Complete, Signed, 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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**Casebook Signature Form**

|    |                    |                                      |
|----|--------------------|--------------------------------------|
| 1. | Casebook Signature | <a href="#">Click Here to Enable</a> |
|----|--------------------|--------------------------------------|

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**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

| Name              | Signature Meaning | Date  | Type | Action |
|-------------------|-------------------|---|------|--------|
| Cristiano Zerbini | Approved          | Mar-04-2021 12:12:52 (UTC-03:00) City of Buenos Aires | BOOK | Signed |

**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.

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262089

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

**Form:** INCLUSION/EXCLUSION CRITERIA - 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 | Oct-06-2020 13:20:41 (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 Oct/09/2020

**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  
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| Form | Oct-09-2020 16:39:09 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) | Not Done |

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| Form | Oct-09-2020 16:41:24 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) | Not Applicable |

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| 5.i  | Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6)<br>(b) (4) | Not Done |



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

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| 5.j  | Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6)<br>(b) (4) | Not Done |

**Header Text:** C4591001

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

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

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| 5.j  | Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6)<br>(b) (4) | Not Done |

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| 5.j  | Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6)<br>(b) (4) | Not Done |

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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments  
on Oct/09/2020

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

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**Subject No:** 12262089

**Subject Initials:** ---

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

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| Item | Date  | User             | Comment        |
|------|---|------------------|----------------|
| Form | Oct-09-2020 16:42:47 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) | Not Applicable |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

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on Oct/09/2020

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**Subject No:** 12262089

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| Item | Date  | User                        | Comment        |
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| 2    | Oct-09-2020 16:42:47 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6)<br>(b) (4) | Not Applicable |

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| 3    | Oct-09-2020 16:42:47 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6)<br>(b) (4) | Not Applicable |



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**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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| Form | Oct-09-2020 16:42:59 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) | Not Applicable |

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| 2    | Oct-09-2020 16:42:59 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6)<br>[Redacted] | Not Applicable |

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| Form | Oct-09-2020 16:43:12 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) | Not Done |



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| 1    | Oct-09-2020 16:43:12 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6)<br>(b) (4) | Not Done |

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| 2    | Oct-09-2020 16:43:12 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6)<br>(b) (4) | Not Done |

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

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| 1    | Dec-29-2020 10:15:53 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) | Not Done |

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| 2    | Dec-29-2020 10:15:53 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) | Not Done |

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| 3    | Dec-29-2020 10:15:53 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) | Not Done |



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| 4    | Dec-29-2020 10:15:53 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) | Not Done |

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| 5    | Dec-29-2020 10:15:53 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) | Not Done |

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| 8    | Dec-29-2020 10:15:53 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) | Not Done |

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| 9    | Dec-29-2020 10:15:53 (UTC-03:00) City of Buenos Aires | (b) (4), (b) (6) | Not Done |

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

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

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

- CRF\_Sign

| Name              | Signature Meaning | Date  | Type | Action |
|-------------------|-------------------|---|------|--------|
| Cristiano Zerbini | Approved          | Mar-04-2021 12:12:52 (UTC-03:00) City of Buenos Aires | BOOK | Signed |

**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-17-2021 15:31:24 (UTC-03:00) City of Buenos Aires |  | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|                   |          |   |      |        |
|-------------------|----------|---|------|--------|
| Cristiano Zerbini | Approved | Jan-30-2021 11:10:10 (UTC-03:00) City of Buenos Aires | BOOK | Signed |
|-------------------|----------|---|------|--------|

**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-27-2021 15:50:02 (UTC-03:00) City of Buenos Aires |  | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

|                   |          |   |      |        |
|-------------------|----------|---|------|--------|
| Cristiano Zerbini | Approved | Jan-23-2021 08:42:00 (UTC-03:00) City of Buenos Aires | BOOK | Signed |
|-------------------|----------|---|------|--------|

**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-10-2020 16:50:39 (UTC-03:00) City of Buenos Aires |  | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|                   |          |   |      |        |
|-------------------|----------|---|------|--------|
| Cristiano Zerbini | Approved | Nov-13-2020 11:36:00 (UTC-03:00) City of Buenos Aires | BOOK | Signed |
|-------------------|----------|---|------|--------|

**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.

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)



**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1226

**Subject No:** 12262089

**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

[Back to Form](#)

*1. Select appropriate response - Protocol version*

| Date   | Location        | User             | Value                             | Reason        |
|--|-----------------|------------------|-----------------------------------|---------------|
| Oct-06-2020 13:17:50<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>08 SEP 2020 | Initial Entry |

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

| Date   | Location        | User             | Value                                 | Reason        |
|--|-----------------|------------------|---------------------------------------|---------------|
| Oct-06-2020 13:17:50<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>STAGE 3 COHORTS | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1226

**Subject No:** 12262089

**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        |
|--|-----------------|------------------|---|---------------|
| Oct-06-2020 13:17:56<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>OBTAINED<br>Date Written Consent Obtained<br><br>Oct/6/2020 | Initial Entry |

Header Text: C4591001

Visit: COHORT\_SELECTION

Form Version: 15-Sep-2020 21:54

Site No: 1226

Subject No: 12262089

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                         |
|--|-----------------|-------------------------|--------------------------------|--------------------------------|
| Oct-06-2020 13:17:40<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>12262089 | Item copied from previous form |

**2. Birth Date:**

| Date   | Location        | User                    | Value                              | Reason           |
|--|-----------------|-------------------------|------------------------------------|------------------|
| Oct-06-2020 13:17:37<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>(b) (6)/1975 | Enrollment Entry |

**3. Sex:**

| Date   | Location        | User             | Value                        | Reason        |
|--|-----------------|------------------|------------------------------|---------------|
| Oct-06-2020 13:20:00<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>FEMALE | Initial Entry |

**4. Ethnicity:**

| Date   | Location        | User             | Value  | Reason        |
|--|-----------------|------------------|--|---------------|
| Oct-06-2020 13:20:00<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN | Initial Entry |

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

| Date   | Location        | User             | Value  | Reason        |
|--|-----------------|------------------|--|---------------|
| Oct-06-2020 13:20:00<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>BLACK OR AFRICAN AMERICAN<br>WHITE | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262089

**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-06-2020 13:20:22<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Oct/6/2020 | Initial Entry |

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262089

**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        |
|--|-----------------|------------------|----------------------------------|---------------|
| Oct-06-2020 13:20:51<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Oct/6/2020 | Initial Entry |

**2. Phase of Disposition:**

| Date   | Location        | User                    | Value                           | Reason        |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Oct-06-2020 13:20:51<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SCREENING | Initial Entry |

**3. Status:**

| Date   | Location        | User             | Value                           | Reason        |
|--|-----------------|------------------|---------------------------------|---------------|
| Oct-06-2020 13:20:51<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>COMPLETED | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1226**Subject No:** 12262089**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - 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[Back to Form](#)*I.a*

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Oct-06-2020 13:21:54<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Line/MH Number:</b> 1<br><b>Medical History Term:</b> Bilateral tubal ligation<br><b>Start Date:</b> UNK/UNK/2006<br><b>Ongoing:</b> NO<br>End Date:<br>UNK/UNK/2006 | Initial Entry |

*I.a Line/MH Number:*

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Oct-06-2020 13:21:54<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>1 | Initial Entry |

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

| Date   | Location        | User             | Value  | Reason        |
|--|-----------------|------------------|--|---------------|
| Oct-06-2020 13:21:54<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Bilateral tubal ligation | Initial Entry |

*I.a Start Date:*

| Date   | Location        | User             | Value                              | Reason        |
|--|-----------------|------------------|------------------------------------|---------------|
| Oct-06-2020 13:21:54<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>UNK/UNK/2006 | Initial Entry |

*I.a Ongoing:*

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262089

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

**Form:** GENERAL MEDICAL HISTORY - 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        |
|---|-----------------|------------------|---|---------------|
| Oct-06-2020 13:21:54<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO<br>End Date:<br><br>UNK/UNK/2006 | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

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

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1226

**Subject No:** 12262089

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

**Form:** HIV STATUS - 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 - What is the subject HIV status?*

| Date   | Location        | User             | Value   | Reason        |
|--|-----------------|------------------|---|---------------|
| Oct-06-2020 13:22:03<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>The subject is NOT known to be HIV POSITIVE | Initial Entry |



Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:56

Site No: 1226

Subject No: 12262089

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        |
|--|-----------------|------------------|----------------------------------|---------------|
| Oct-06-2020 13:22:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>Oct/6/2020 | Initial Entry |

**2. Weight:**

| Date   | Location        | User             | Value                      | Reason        |
|--|-----------------|------------------|----------------------------|---------------|
| Oct-06-2020 13:22:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>56.0 | Initial Entry |

**3. Unit:**

| Date   | Location        | User             | Value                    | Reason        |
|--|-----------------|------------------|--------------------------|---------------|
| Oct-06-2020 13:22:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>kg | Initial Entry |

**4. Height:**

| Date   | Location        | User             | Value                       | Reason        |
|--|-----------------|------------------|-----------------------------|---------------|
| Oct-06-2020 13:22:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>161.0 | Initial Entry |

**5. Unit:**

| Date   | Location        | User             | Value                    | Reason        |
|--|-----------------|------------------|--------------------------|---------------|
| Oct-06-2020 13:22:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>cm | Initial Entry |

**6. Body Mass Index:**

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:56

Site No: 1226

Subject No: 12262089

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

|  |                 |                         |                            |               |
|--|-----------------|-------------------------|----------------------------|---------------|
| Oct-06-2020 13:22:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>21.6 | Initial Entry |
|--|-----------------|-------------------------|----------------------------|---------------|

7.a

| Date   | Location        | User             | Value   | Reason        |
|--|-----------------|------------------|---|---------------|
| Oct-06-2020 13:22:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Record Identifier::</b> 1<br><b>Temperature:</b> 36.5<br><b>Temperature Unit:</b> C<br><b>Temperature Locat ion::</b> FOREHEAD | Initial Entry |

7.a Record Identifier:

| Date   | Location        | User             | Value                   | Reason        |
|--|-----------------|------------------|-------------------------|---------------|
| Oct-06-2020 13:22:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>1 | Initial Entry |

7.a Temperature:

| Date   | Location        | User             | Value                      | Reason        |
|--|-----------------|------------------|----------------------------|---------------|
| Oct-06-2020 13:22:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>36.5 | Initial Entry |

7.a Unit:

| Date   | Location        | User             | Value                   | Reason        |
|--|-----------------|------------------|-------------------------|---------------|
| Oct-06-2020 13:22:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>C | Initial Entry |

7.a Temperature Location:

| Date   | Location        | User             | Value                          | Reason        |
|--|-----------------|------------------|--------------------------------|---------------|
| Oct-06-2020 13:22:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>FOREHEAD | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

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: 12262089

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        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Oct-06-2020 13:23:18<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>URINALYSIS | Initial Entry |

**2. Lab Sub-Panel:**

| Date   | Location        | User                    | Value                           | Reason        |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Oct-06-2020 13:23:18<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>PREGNANCY | Initial Entry |

**3. Collection Date:**

| Date   | Location        | User             | Value                            | Reason        |
|--|-----------------|------------------|----------------------------------|---------------|
| Oct-06-2020 13:23:18<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Oct/6/2020 | Initial Entry |

**4. Laboratory Name and Address (Derived)**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Oct-06-2020 13:23:18<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>STUDY SITE | Initial Entry |

**5. Specimen Type:**

| Date   | Location        | User                    | Value                       | Reason        |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Oct-06-2020 13:23:18<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>URINE | Initial Entry |

**6.a**

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

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: 12262089

Subject Initials: ---

Generated By: (b) (4)

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

|  |                 |                         |  |               |
|--|-----------------|-------------------------|--|---------------|
| Oct-06-2020 13:23:18<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Choriogonadotropin Beta_PX113<br><b>Result::</b> NEGATIVE<br><b>Not Done::</b> | Initial Entry |
|--|-----------------|-------------------------|--|---------------|

6.a Sponsor ID:

| Date   | Location        | User                    | Value                     | Reason        |
|--|-----------------|-------------------------|---------------------------|---------------|
| Oct-06-2020 13:23:18<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>113 | Initial Entry |

6.a Test:

| Date   | Location        | User             | Value   | Reason        |
|--|-----------------|------------------|---|---------------|
| Oct-06-2020 13:23:18<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Choriogonadotropin Beta_PX113 | Initial Entry |

6.a Result:

| Date   | Location        | User             | Value                          | Reason        |
|--|-----------------|------------------|--------------------------------|---------------|
| Oct-06-2020 13:23:18<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NEGATIVE | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262089

**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        |
|--|-----------------|------------------|----------------------------------|---------------|
| Oct-06-2020 13:24:01<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Oct/6/2020 | Initial Entry |

**2. Randomization Number:**

| Date   | Location        | User             | Value                        | Reason        |
|--|-----------------|------------------|------------------------------|---------------|
| Oct-06-2020 13:24:01<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>103777 | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (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: 12262089

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        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Oct-07-2020 08:24:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                       | Reason        |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Oct-07-2020 08:24:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value  | Reason   |
|--|-----------------|---------------------------|--|--|
| Oct-07-2020 08:24:55<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted   | Close Auto Query   |
| Oct-07-2020 08:24:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate   | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Oct-07-2020 08:24:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Oct/6/2020 | Initial Entry  |

**5.a**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Oct-07-2020 08:24:55<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BPWZ3D | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (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: 12262089

Subject Initials: ---

Generated By: (b) (4)

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

|  |  |                  |  |  |
|--|--|------------------|--|--|
|  |  | (b) (4), (b) (6) |  |  |
|--|--|------------------|--|--|

5.a Sample ID

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Oct-07-2020 08:24:55<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>BPWZ3D | Initial Entry |

5.b

| Date   | Location        | User                | Value                                   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Oct-07-2020 08:25:02<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>Sample ID: BRVC5K | Initial Entry |

5.b Sample ID

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Oct-07-2020 08:25:02<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>BRVC5K | Initial Entry |

5.c

| Date   | Location        | User                | Value                                   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Oct-07-2020 08:25:08<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>Sample ID: BRVC5J | Initial Entry |

5.c Sample ID

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Oct-07-2020 08:25:08<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>BRVC5J | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1226**Subject No:** 12262089**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[Back to Form](#)**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Oct-07-2020 09:09:30<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                            | Reason        |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Oct-07-2020 09:09:30<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                              | Value  | Reason  |
|---|-----------------|-----------------------------------|--|---|
| Oct-07-2020 09:09:38<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery)         | Query 1: Deleted   | Close Auto Query  |
| Oct-07-2020 09:09:30<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery)         | Query 1: Candidate   | 'Sample Collected?'<br>is Yes, however no<br>barcodes are<br>entered. Please<br>review and correct<br>as appropriate. |
| Oct-07-2020 09:09:30<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)<br>[REDACTED] | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Oct/6/2020 | Initial Entry   |

**5.a**

| Date  | Location        | User                              | Value  | Reason        |
|---|-----------------|-----------------------------------|--|---------------|
| Oct-07-2020 09:09:38<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)<br>[REDACTED] | <b>Data Entry:</b><br><b>Sample ID:</b> BPVZ36 | Initial Entry |



**Header Text:** C4591001

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

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

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

|  |  |                  |  |  |
|--|--|------------------|--|--|
|  |  | (b) (4), (b) (6) |  |  |
|--|--|------------------|--|--|

**5.a Sample ID**

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Oct-07-2020 09:09:38<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BPVZ36 | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12262089

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        |
|--|-----------------|------------------|--------------------------|---------------|
| Oct-06-2020 13:24:45<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2. Treatment Name**

| Date   | Location        | User                    | Value                                 | Reason        |
|--|-----------------|-------------------------|---------------------------------------|---------------|
| Oct-06-2020 13:24:45<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>BLINDED THERAPY | Initial Entry |

**3. Formulation:**

| Date   | Location        | User                    | Value                           | Reason        |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Oct-06-2020 13:24:45<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INJECTION | Initial Entry |

**4. Dose Date Time:**

| Date   | Location        | User             | Value                                  | Reason        |
|--|-----------------|------------------|--|---------------|
| Oct-06-2020 13:24:45<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Oct/6/2020 11:40 | Initial Entry |

**5. Anatomical Location:**

| Date   | Location        | User                    | Value                                | Reason        |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Oct-06-2020 13:24:45<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DELTOID MUSCLE | Initial Entry |

**6. Body Side:**

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12262089

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

|  |                 |                  |                            |               |
|--|-----------------|------------------|----------------------------|---------------|
| Oct-06-2020 13:24:45<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>LEFT | Initial Entry |
|--|-----------------|------------------|----------------------------|---------------|

7. Route:

| Date   | Location        | User                    | Value                               | Reason        |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Oct-06-2020 13:24:45<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INTRAMUSCULAR | Initial Entry |

10. Timeframe Subject Was Observed

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Oct-06-2020 13:24:45<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>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        |
|--|-----------------|------------------|---------------------------|---------------|
| Oct-06-2020 13:24:45<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262089

**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        |
|---|-----------------|------------------|---|---------------|
| Oct-06-2020 13:24:56<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO - REACTOGENICITY E-DI<br>ARY NOT COLLECTED FOR<br>THIS SUBJECT | Initial Entry |

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1226

**Subject No:** 12262089

**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   |
|---|-----------------|------------------|------------------------------|--|
| Nov-11-2020<br>19:39:22<br>(UTC-03:00)<br>City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query<br>2: Clo<br>sed       | Response satisfies<br>query  |
| Nov-11-2020<br>14:50:24<br>(UTC-03:00)<br>City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query<br>2: An<br>swere<br>d | The alert was<br>entered late into the<br>system by the<br>participant. The<br>symptoms refer to<br>the visit of COVID<br>performed in<br>09oct2020.   |
| Nov-10-2020<br>05:58:54<br>(UTC-03:00)<br>City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query<br>2: Op<br>ened       | Illness eduary: As<br>per Illness eduary<br>records, subject<br>reported "Yes" for<br>the COVID-19<br>symptoms or<br>diagnosis on<br>13OCT2020. But no<br>corresponding<br>COVID Illness visit<br>indicate symptoms<br>present at this date.<br>Pls update Covid<br>illness visit or<br>clarify. |
| Nov-09-2020<br>02:40:02<br>(UTC-03:00)<br>City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query<br>1: Clo<br>sed       | As per site<br>confirmation -<br>updated PD tracker  |
| Nov-07-2020<br>08:52:59<br>(UTC-03:00)                            | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query<br>1: An<br>swere      | The date is correct.<br>The subject came<br>out of the window  |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1226

**Subject No:** 12262089

**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

|  |   |                         |                                    |  |
|--|---|-------------------------|------------------------------------|--|
| City of Buenos Aires   |   |                         | d                                  | due unavailability.  |
| Nov-07-2020<br>04:04:01<br>(UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFE SDQ PROD<br>(b) (4) | Query 1: Opened                    | PDQ: Date of visit at V2_VAX2_L is out of window for 8 days from V1_DAY1_VAX1_L Dose Date. Please verify and update. Else, confirm in query response appropriately.<br>(b) (4) |
| Nov-06-2020<br>16:36:03<br>(UTC-03:00)<br>City of Buenos Aires | ACV0PFEINFP6000                           | (b) (4), (b) (6)        | <b>Data Entry</b><br>: Nov/6 /2020 | Initial Entry  |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 10-Oct-2020 16:01

Site No: 1226

Subject No: 12262089

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        |
|--|-----------------|---------------------|----------------------------------|---------------|
| Nov-06-2020 16:37:00<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/6/2020 | Initial Entry |

**2.a**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-06-2020 16:37:00<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Record Identifier::</b> 1<br><b>Temperature:</b> 36.5<br><b>Temperature Unit:</b> C<br><b>Temperature Location::</b> FOREHE<br>AD | Initial Entry |

**2.a Record Identifier:**

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Nov-06-2020 16:37:00<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>1 | Initial Entry |

**2.a Temperature:**

| Date   | Location        | User                | Value                      | Reason        |
|--|-----------------|---------------------|----------------------------|---------------|
| Nov-06-2020 16:37:00<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>36.5 | Initial Entry |

**2.a Unit:**

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Nov-06-2020 16:37:00<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>C | Initial Entry |

**2.a Temperature Location:**

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1226

**Subject No:** 12262089

**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        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-06-2020 16:37:00<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>FOREHEAD | Initial Entry |



Header Text: C4591001

Visit: V2\_VAX2\_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

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: 12262089

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-06-2020 16:37:23<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>URINALYSIS | Initial Entry |

**2. Lab Sub-Panel:**

| Date   | Location        | User                    | Value                           | Reason        |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Nov-06-2020 16:37:23<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>PREGNANCY | Initial Entry |

**3. Collection Date:**

| Date   | Location        | User                | Value                            | Reason        |
|--|-----------------|---------------------|----------------------------------|---------------|
| Nov-06-2020 16:37:23<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>Nov/6/2020 | Initial Entry |

**4. Laboratory Name and Address (Derived)**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Nov-06-2020 16:37:23<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>STUDY SITE | Initial Entry |

**5. Specimen Type:**

| Date   | Location        | User                    | Value                       | Reason        |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Nov-06-2020 16:37:23<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>URINE | Initial Entry |

**6.a**

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

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: 12262089

Subject Initials: ---

Generated By: (b) (4)

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

|  |                 |                         |  |               |
|--|-----------------|-------------------------|--|---------------|
| Nov-06-2020 16:37:23<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 113<br><b>Test::</b> Choriogonadotropin Beta_PX113<br><b>Result::</b> NEGATIVE<br><b>Not Done::</b> | Initial Entry |
|--|-----------------|-------------------------|--|---------------|

6.a Sponsor ID:

| Date   | Location        | User                    | Value                     | Reason        |
|--|-----------------|-------------------------|---------------------------|---------------|
| Nov-06-2020 16:37:23<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>113 | Initial Entry |

6.a Test:

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-06-2020 16:37:23<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Choriogonadotropin Beta_PX113 | Initial Entry |

6.a Result:

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Nov-06-2020 16:37:23<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NEGATIVE | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (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: 12262089

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        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Nov-07-2020 08:55:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Nov-07-2020 08:55:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value  | Reason   |
|--|-----------------|---------------------------|--|--|
| Nov-07-2020 09:21:51<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted   | Close Auto Query   |
| Nov-07-2020 08:55:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate   | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Nov-07-2020 08:55:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Nov/6/2020 | Initial Entry  |

**5.a**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-07-2020 09:21:51<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BR690Z | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (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:** 12262089

**Subject Initials:** ---

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

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

|  |  |                  |  |  |
|--|--|------------------|--|--|
|  |  | (b) (4), (b) (6) |  |  |
|--|--|------------------|--|--|

**5.a Sample ID**

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Nov-07-2020 09:21:51<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BR690Z | Initial Entry |

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12262089

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        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-06-2020 16:37:53<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2. Treatment Name**

| Date   | Location        | User                    | Value                                 | Reason        |
|--|-----------------|-------------------------|---------------------------------------|---------------|
| Nov-06-2020 16:37:53<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>BLINDED THERAPY | Initial Entry |

**3. Formulation:**

| Date   | Location        | User                    | Value                           | Reason        |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Nov-06-2020 16:37:53<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INJECTION | Initial Entry |

**4. Dose Date Time:**

| Date   | Location        | User                | Value                                  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-06-2020 16:37:53<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/6/2020 10:16 | Initial Entry |

**5. Anatomical Location:**

| Date   | Location        | User                    | Value                                | Reason        |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Nov-06-2020 16:37:53<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DELTOID MUSCLE | Initial Entry |

**6. Body Side:**

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12262089

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

|  |                 |                     |                            |               |
|--|-----------------|---------------------|----------------------------|---------------|
| Nov-06-2020 16:37:53<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>LEFT | Initial Entry |
|--|-----------------|---------------------|----------------------------|---------------|

7. Route:

| Date   | Location        | User                    | Value                               | Reason        |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Nov-06-2020 16:37:53<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INTRAMUSCULAR | Initial Entry |

10. Timeframe Subject Was Observed

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-06-2020 16:37:53<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>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        |
|--|-----------------|---------------------|---------------------------|---------------|
| Nov-06-2020 16:37:53<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262089

**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        |
|---|-----------------|--------------------------------|-----------------------------------|---------------|
| Dec-10-2020 16:50:39<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>[REDACTED] | <b>Data Entry:</b><br>Dec/10/2020 | Initial Entry |

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

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

Subject No: 12262089

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        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Dec-11-2020 09:16:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                       | Reason        |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Dec-11-2020 09:16:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value   | Reason   |
|--|-----------------|---------------------------|---|--|
| Dec-11-2020 09:17:04<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted  | Close Auto Query   |
| Dec-11-2020 09:16:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate  | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Dec-11-2020 09:16:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)          | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Dec/10/2020 | Initial Entry  |

**5.a**

| Date   | Location        | User             | Value  | Reason        |
|--|-----------------|------------------|--|---------------|
| Dec-11-2020 09:17:04<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BRGTGH | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (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: 12262089

Subject Initials: ---

Generated By: (b) (4)

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

5.a Sample ID

| Date   | Location        | User             | Value                        | Reason        |
|--|-----------------|------------------|------------------------------|---------------|
| Dec-11-2020 09:17:04<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>BRGTGH | Initial Entry |

5.b

| Date   | Location        | User             | Value                                   | Reason        |
|--|-----------------|------------------|---|---------------|
| Dec-11-2020 09:17:16<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>Sample ID: BSF1YT | Initial Entry |

5.b Sample ID

| Date   | Location        | User             | Value                        | Reason        |
|--|-----------------|------------------|------------------------------|---------------|
| Dec-11-2020 09:17:16<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>BSF1YT | Initial Entry |

5.c

| Date   | Location        | User             | Value                                   | Reason        |
|--|-----------------|------------------|---|---------------|
| Dec-11-2020 09:17:23<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>Sample ID: BSF1YV | Initial Entry |

5.c Sample ID

| Date   | Location        | User             | Value                        | Reason        |
|--|-----------------|------------------|------------------------------|---------------|
| Dec-11-2020 09:17:23<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>BSF1YV | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Oct/09/2020**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:** 12262089**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   |
|--|-----------------|---------------------------|----------------------------------|--|
| Oct-09-2020 16:40:02<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted                 | Close Auto Query   |
| Oct-09-2020 16:38:16<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 2: Deleted                 | Close Auto Query   |
| Oct-09-2020 16:37:24<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(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.          |
| Oct-09-2020 16:37:24<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(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. |
| Oct-09-2020 16:37:24<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>Oct/9/2020 | Initial Entry  |

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

| Date   | Location        | User                    | Value                         | Reason        |
|--|-----------------|-------------------------|-------------------------------|---------------|
| Oct-09-2020 16:37:24<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>COVID_A | Initial Entry |

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020**Form Version:** 15-Sep-2020 21:55**Site No:** 1226**Subject No:** 12262089**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        |
|--|-----------------|---------------------|----------------------------------|---------------|
| Oct-09-2020 16:38:16<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Oct/9/2020 | Initial Entry |

**2. Date of First Symptom Started:**

| Date   | Location        | User                | Value                            | Reason        |
|--|-----------------|---------------------|----------------------------------|---------------|
| Oct-09-2020 16:38:16<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Oct/7/2020 | Initial Entry |

**3. Symptoms Ongoing?**

| Date   | Location        | User             | Value   | Reason          |
|--|-----------------|------------------|---|-----------------|
| Oct-14-2020 14:05:18<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO<br>Date of Last Symptom Resolved:<br>Oct/11/2020 | New Information |
| Oct-09-2020 16:38:16<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES   | Initial Entry   |

**4.a**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Oct-09-2020 16:38:16<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptoms:</b> FEVER<br><b>Symptom Present:</b> NO | Initial Entry |

**4.a Symptoms:**

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020**Form Version:** 15-Sep-2020 21:55**Site No:** 1226**Subject No:** 12262089**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

|  |                 |                     |                             |               |
|--|-----------------|---------------------|-----------------------------|---------------|
| Oct-09-2020 16:38:16<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>FEVER | Initial Entry |
|--|-----------------|---------------------|-----------------------------|---------------|

**4.a Was symptom present?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-09-2020 16:38:16<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**4.b**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Oct-09-2020 16:38:16<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptoms:</b> NEW OR INCREASED COUGH<br><b>Symptom P present:</b> NO | Initial Entry |

**4.b Symptoms:**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Oct-09-2020 16:38:16<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NEW OR INCREASED COUGH | Initial Entry |

**4.b Was symptom present?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-09-2020 16:38:16<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**4.c**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Oct-09-2020 16:38:16<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptoms:</b> NEW OR INCREASED SHORTNESS OF B | Initial Entry |

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262089

Subject Initials: ---

Generated By: (b) (4)

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

|  |  |  |                     |  |
|--|--|--|---------------------|--|
|  |  |  | REATH               |  |
|  |  |  | Symptom Present: NO |  |

4.c Symptoms:

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Oct-09-2020 16:38:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NEW OR INCREASED SHORTNESS OF BREATH | Initial Entry |

4.c Was symptom present?

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Oct-09-2020 16:38:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

4.d

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Oct-09-2020 16:38:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Symptoms: CHILLS<br>Symptom Present: NO | Initial Entry |

4.d Symptoms:

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Oct-09-2020 16:38:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>CHILLS | Initial Entry |

4.d Was symptom present?

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Oct-09-2020 16:38:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262089

Subject Initials: ---

Generated By: (b) (4)

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

4.e

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Oct-09-2020 16:38:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Symptom NEW OR INCREASED MUSCLE PAIN<br>Symptom NO<br>Present: | Initial Entry |

4.e Symptoms:

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Oct-09-2020 16:38:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NEW OR INCREASED MUSCLE PAIN | Initial Entry |

4.e Was symptom present?

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Oct-09-2020 16:38:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

4.f

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Oct-09-2020 16:38:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Symptoms NEW LOSS OF TASTE OR SMELL<br>Symptom NO<br>Present: | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262089

Subject Initials: ---

Generated By: (b) (4)

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

4.f Symptoms:

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Oct-09-2020 16:38:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NEW LOSS OF TASTE OR SMLL | Initial Entry |

4.f Was symptom present?

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Oct-09-2020 16:38:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

4.g

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Oct-09-2020 16:38:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptom</b> NEW OR INCREASED SORE THROAT<br><b>Symptom</b> YES<br><b>Present:</b> | Initial Entry |

4.g Symptoms:

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Oct-09-2020 16:38:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NEW OR INCREASED SORE THROAT | Initial Entry |

4.g Was symptom present?

| Date  | Location        | User             | Value                     | Reason        |
|---|-----------------|------------------|---------------------------|---------------|
| Oct-09-2020 16:38:16 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

4.h

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020**Form Version:** 15-Sep-2020 21:55**Site No:** 1226**Subject No:** 12262089**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

|  |                 |                     |   |               |
|--|-----------------|---------------------|---|---------------|
| Oct-09-2020 16:38:16<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptoms:</b> DIARRHEA<br><b>Symptom Present:</b> NO | Initial Entry |
|--|-----------------|---------------------|---|---------------|

**4.h Symptoms:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Oct-09-2020 16:38:16<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>DIARRHEA | Initial Entry |

**4.h Was symptom present?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-09-2020 16:38:16<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**4.i**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Oct-09-2020 16:38:16<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptoms:</b> VOMITING<br><b>Symptom Present:</b> NO | Initial Entry |

**4.i Symptoms:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Oct-09-2020 16:38:16<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>VOMITING | Initial Entry |

**4.i Was symptom present?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-09-2020 16:38:16<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**5.a**



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Oct-09-2020 16:38:25<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptoms - Other:</b> headache | Initial Entry |

**5.a Symptoms - Other Text:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Oct-09-2020 16:38:25<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>headache | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Oct/09/2020

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: 12262089

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        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Oct-09-2020 16:39:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**2. Specimen Type:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Oct-09-2020 16:39:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**3. Specimen Collection Location:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Oct-09-2020 16:39:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**4. Assay Code and Description:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Oct-09-2020 16:39:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5. Device Type:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Oct-09-2020 16:39:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**6. Trade Name:**

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Oct/09/2020

**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:** 12262089

**Subject Initials:** ---

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

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

|   |                 |                     |                                |               |
|---|-----------------|---------------------|--------------------------------|---------------|
| Oct-09-2020 16:39:09<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |
|---|-----------------|---------------------|--------------------------------|---------------|

**7. Test Result:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Oct-09-2020 16:39:09<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**8. Comments/Findings/Details:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Oct-09-2020 16:39:09<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**9. Trade Name Other, Specify:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Oct-09-2020 16:39:09<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1226**Subject No:** 12262089**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[Back to Form](#)**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Oct-09-2020 16:39:42<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                                 | Reason        |
|--|-----------------|-------------------------|---------------------------------------|---------------|
| Oct-09-2020 16:39:42<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB_SELF | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-09-2020 16:39:42<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>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        |
|--|-----------------|---------------------|---|---------------|
| Oct-09-2020 16:39:42<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>swab collection performed at the site | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

**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:** 12262089

**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        |
|---|-----------------|----------------------|----------------------------|---------------|
| Oct-09-2020 16:40:02 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                 | Value                            | Reason        |
|---|-----------------|----------------------|----------------------------------|---------------|
| Oct-09-2020 16:40:02 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                   | Value  | Reason   |
|---|-----------------|------------------------|--|--|
| Oct-09-2020 16:40:15 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted   | Close Auto Query   |
| Oct-09-2020 16:40:02 (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-09-2020 16:40:02 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)    | <b>Data Entry:</b><br>YES<br>Date of Collection:<br>Oct/9/2020 | Initial Entry  |

**5.a**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Oct-09-2020 16:40:15 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BPWZF1 | Initial Entry |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

**Site No:** 1226

**Subject No:** 12262089

**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

**5.a Sample ID**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Oct-09-2020 16:40:15<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>BPWZF1 | Initial Entry |

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/09/2020

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262089

Subject Initials: ---

Generated By: (b) (4)

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

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*1.a*

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Oct-09-2020 16:40:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Type of Practitioner:</b> SPECIALIST<br><b>Occurrence of Visits or Contacts:</b> NO | Initial Entry |

*1.a Physician or Healthcare Professional:*

| Date   | Location        | User                | Value                            | Reason        |
|--|-----------------|---------------------|----------------------------------|---------------|
| Oct-09-2020 16:40:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>SPECIALIST | Initial Entry |

*1.a Occurrence of Visits or Contacts:*

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-09-2020 16:40:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

*1.b*

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Oct-09-2020 16:40:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Type of Practitioner:</b> EMERGENCY ROOM<br><b>Occurrence of Visits or Contacts:</b> NO | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/09/2020

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**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        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Oct-09-2020 16:40:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>EMERGENCY ROOM | Initial Entry |

***1.b Occurrence of Visits or Contacts:***

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-09-2020 16:40:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

***1.c***

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Oct-09-2020 16:40:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN<br><b>Occurrence of Visits or Contacts:</b> YES<br><i>Number of Visits or Contacts:</i><br>1 | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)



**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/09/2020**Form Version:** 15-Sep-2020 21:53**Form Status:** Data Complete, Frozen, Verified**Site No:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject No:** 12262089**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54***I.c Physician or Healthcare Professional:***

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Oct-09-2020 16:40:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>PRIMARY CARE PHYSICIAN | Initial Entry |

***I.c Occurrence of Visits or Contacts:***

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Oct-09-2020 16:40:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES<br><i>Number of Visits or Contacts:</i><br>1 | Initial Entry |

***I.d***

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Oct-09-2020 16:40:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Type of Practitioner</b> URGENT<br>: CARE<br><b>Occurrence of Visits</b> NO<br><b>or Contacts:</b> | Initial Entry |

***I.d Physician or Healthcare Professional:***

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Oct-09-2020 16:40:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>URGENT CARE | Initial Entry |

***I.d Occurrence of Visits or Contacts:***

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-09-2020 16:40:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

***I.e***

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/09/2020

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262089

Subject Initials: ---

Generated By: (b) (4)

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

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Oct-09-2020 16:40:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Type of Practitioner:</b> TELEPHONE CONSULTATION<br><b>Occurrence of Visits or Contacts:</b> NO | Initial Entry |

*I.e Physician or Healthcare Professional:*

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Oct-09-2020 16:40:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>TELEPHONE CONSULTATION | Initial Entry |

*I.e Occurrence of Visits or Contacts:*

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-09-2020 16:40:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

*I.f*

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Oct-09-2020 16:40:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Type of Practitioner:</b> OTHER<br><b>Occurrence of Visits or Contacts:</b> NO | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Oct/09/2020

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

**1.f Physician or Healthcare Professional:**

| Date   | Location        | User                | Value                       | Reason        |
|--|-----------------|---------------------|-----------------------------|---------------|
| Oct-09-2020 16:40:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>OTHER | Initial Entry |

**1.f Occurrence of Visits or Contacts:**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-09-2020 16:40:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

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

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-09-2020 16:40:48<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: RESPIRATORY TREATMENT - eCRF Audit Trail History on Oct/09/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262089

Subject Initials: ---

Generated By: (b) (4)

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

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**1. What is the treatment Identifier?**

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Oct-09-2020 16:40:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

**2. Concomitant Non-drug Treatment Pre-specified:**

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Oct-09-2020 16:40:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

**3. Treatment:**

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Oct-09-2020 16:40:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

**4. Treatment:**

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Oct-09-2020 16:40:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

**5. Start Date:**

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Oct-09-2020 16:40:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

**6. Ongoing?**

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History on Oct/09/2020

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

|   |                 |                     |                                      |               |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-09-2020 16:40:59<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |
|---|-----------------|---------------------|--------------------------------------|---------------|

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History  
on Oct/09/2020

**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:** 12262089

**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        |
|---|-----------------|-------------------------|--|---------------|
| Oct-09-2020 16:41:15<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>POTENTIAL COVID-19 ILLNES<br>S | Initial Entry |

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

| Date  | Location        | User                | Value                    | Reason        |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-09-2020 16:41:15<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**3. Toxicity Grade:**

| Date  | Location        | User                | Value                   | Reason        |
|---|-----------------|---------------------|-------------------------|---------------|
| Oct-09-2020 16:41:15<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>1 | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Oct/09/2020

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**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        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Oct-09-2020 16:41:24<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

**2. Subcategory of Clinical Event:**

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Oct-09-2020 16:41:24<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

**3. Was a diagnosis obtained?**

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Oct-09-2020 16:41:24<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

**4. Toxicity Grade:**

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Oct-09-2020 16:41:24<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020**Form Version:** 15-Sep-2020 21:51**Site No:** 1226**Subject No:** 12262089**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[Back to Form](#)**1. Lab Panel:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**2. Laboratory Name and Address**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**3. Collection Date:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**4. Specimen Type:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.a**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Oct-09-2020 16:41:42<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> Not Done<br><b>Test::</b> Not Done<br><b>Result::</b> Not Done | Initial Entry |



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262089

Subject Initials: ---

Generated By: (b) (4)

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

|  |  |  |                          |          |
|--|--|--|--------------------------|----------|
|  |  |  | <b>Not Done::</b>        | Not Done |
|  |  |  | <b>Lab Normal Range:</b> | Not Done |

5.a Sponsor ID:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.a Test:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.a Result:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.a Not Done:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.a LNMT

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

**5.b**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Oct-09-2020 16:41:42<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> Not Done<br><b>Test::</b> Not Done<br><b>Result::</b> Not Done<br><b>Not Done::</b> Not Done<br><b>Lab Normal Range:</b> Not Done | Initial Entry |

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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: 12262089

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sponsor ID:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.b Test:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.b Result:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.b Not Done:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.b LNMT

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.c

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Sponsor-Defined Identi Not Do | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

**Site No:** 1226

**Subject No:** 12262089

**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>fier:</b>             | ne       |  |
|  |  |  | <b>Test::</b>            | Not Done |  |
|  |  |  |                          | ne       |  |
|  |  |  | <b>Result::</b>          | Not Done |  |
|  |  |  |                          | ne       |  |
|  |  |  | <b>Not Done::</b>        | Not Done |  |
|  |  |  |                          | ne       |  |
|  |  |  | <b>Lab Normal Range:</b> | Not Done |  |
|  |  |  |                          | ne       |  |

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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: 12262089

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sponsor ID:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.c Test:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.c Result:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.c Not Done:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.c LNMT

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.d

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Sponsor-Defined Identi Not Do | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

|  |  |  |                          |              |  |
|--|--|--|--------------------------|--------------|--|
|  |  |  | <b>fier:</b>             | ne           |  |
|  |  |  | <b>Test::</b>            | Not Do<br>ne |  |
|  |  |  | <b>Result::</b>          | Not Do<br>ne |  |
|  |  |  | <b>Not Done::</b>        | Not Do<br>ne |  |
|  |  |  | <b>Lab Normal Range:</b> | Not Do<br>ne |  |

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262089

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sponsor ID:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.d Test:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.d Result:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.d Not Done:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.d LNMT

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.e

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Sponsor-Defined Identi Not Do | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

**Site No:** 1226

**Subject No:** 12262089

**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>fier:</b>             | ne       |  |
|  |  |  | <b>Test::</b>            | Not Done |  |
|  |  |  |                          | ne       |  |
|  |  |  | <b>Result::</b>          | Not Done |  |
|  |  |  |                          | ne       |  |
|  |  |  | <b>Not Done::</b>        | Not Done |  |
|  |  |  |                          | ne       |  |
|  |  |  | <b>Lab Normal Range:</b> | Not Done |  |
|  |  |  |                          | ne       |  |



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262089

Subject Initials: ---

Generated By: (b) (4)

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

5.e Sponsor ID:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.e Test:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.e Result:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.e Not Done:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.e LNMT

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.f

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Sponsor-Defined Identi Not Do | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

**Site No:** 1226

**Subject No:** 12262089

**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>fier:</b>             | ne       |  |
|  |  |  | <b>Test::</b>            | Not Done |  |
|  |  |  |                          | ne       |  |
|  |  |  | <b>Result::</b>          | Not Done |  |
|  |  |  |                          | ne       |  |
|  |  |  | <b>Not Done::</b>        | Not Done |  |
|  |  |  |                          | ne       |  |
|  |  |  | <b>Lab Normal Range:</b> | Not Done |  |
|  |  |  |                          | ne       |  |

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262089

Subject Initials: ---

Generated By: (b) (4)

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

5.f Sponsor ID:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.f Test:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.f Result:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.f Not Done:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.f LNMT

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.g

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Sponsor-Defined Identi Not Do | Initial Entry |

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

|  |  |  |                          |          |  |
|--|--|--|--------------------------|----------|--|
|  |  |  | <b>fier:</b>             | ne       |  |
|  |  |  | <b>Test::</b>            | Not Done |  |
|  |  |  |                          | ne       |  |
|  |  |  | <b>Result::</b>          | Not Done |  |
|  |  |  |                          | ne       |  |
|  |  |  | <b>Not Done::</b>        | Not Done |  |
|  |  |  |                          | ne       |  |
|  |  |  | <b>Lab Normal Range:</b> | Not Done |  |
|  |  |  |                          | ne       |  |

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262089

Subject Initials: ---

Generated By: (b) (4)

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

5.g Sponsor ID:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>Not Done | Initial Entry |

5.g Test:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>Not Done | Initial Entry |

5.g Result:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>Not Done | Initial Entry |

5.g Not Done:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>Not Done | Initial Entry |

5.g LNMT

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:42 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>Not Done | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020**Form Version:** 15-Sep-2020 21:55**Site No:** 1226**Subject No:** 12262089**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[Back to Form](#)**1. Lab Panel:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**2. Laboratory Name and Address**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**3. Collection Date:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**4. Specimen Type:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.a**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Oct-09-2020 16:41:57<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> Not Done<br><b>Test::</b> Not Done<br><b>Result::</b> Not Done | Initial Entry |

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262089

Subject Initials: ---

Generated By: (b) (4)

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

|  |  |  |                          |          |
|--|--|--|--------------------------|----------|
|  |  |  | <b>Not Done::</b>        | Not Done |
|  |  |  | <b>Lab Normal Range:</b> | Not Done |

5.a Sponsor ID:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.a Test:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.a Result:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.a Not Done:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.a LNMT

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

**5.b**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Oct-09-2020 16:41:57<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> Not Done<br><b>Test::</b> Not Done<br><b>Result::</b> Not Done<br><b>Not Done::</b> Not Done<br><b>Lab Normal Range:</b> Not Done | Initial Entry |



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262089

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sponsor ID:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.b Test:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.b Result:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.b Not Done:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.b LNMT

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.c

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Sponsor-Defined Identi Not Do | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

**Site No:** 1226

**Subject No:** 12262089

**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

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|--|--|--|--------------------------|----------|--|
|  |  |  | <b>fier:</b>             | ne       |  |
|  |  |  | <b>Test::</b>            | Not Done |  |
|  |  |  |                          | ne       |  |
|  |  |  | <b>Result::</b>          | Not Done |  |
|  |  |  |                          | ne       |  |
|  |  |  | <b>Not Done::</b>        | Not Done |  |
|  |  |  |                          | ne       |  |
|  |  |  | <b>Lab Normal Range:</b> | Not Done |  |
|  |  |  |                          | ne       |  |

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262089

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sponsor ID:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.c Test:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.c Result:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.c Not Done:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.c LNMT

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.d

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Sponsor-Defined Identi Not Do | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

**Site No:** 1226

**Subject No:** 12262089

**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>fier:</b>             | ne       |  |
|  |  |  | <b>Test::</b>            | Not Done |  |
|  |  |  |                          | ne       |  |
|  |  |  | <b>Result::</b>          | Not Done |  |
|  |  |  |                          | ne       |  |
|  |  |  | <b>Not Done::</b>        | Not Done |  |
|  |  |  |                          | ne       |  |
|  |  |  | <b>Lab Normal Range:</b> | Not Done |  |
|  |  |  |                          | ne       |  |

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

Form Version: 15-Sep-2020 21:55

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Site No: 1226

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Subject No: 12262089

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sponsor ID:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.d Test:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.d Result:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.d Not Done:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.d LNMT

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.e

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Sponsor-Defined Identi Not Do | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

|  |  |  |                          |          |  |
|--|--|--|--------------------------|----------|--|
|  |  |  | <b>fier:</b>             | ne       |  |
|  |  |  | <b>Test::</b>            | Not Done |  |
|  |  |  |                          | ne       |  |
|  |  |  | <b>Result::</b>          | Not Done |  |
|  |  |  |                          | ne       |  |
|  |  |  | <b>Not Done::</b>        | Not Done |  |
|  |  |  |                          | ne       |  |
|  |  |  | <b>Lab Normal Range:</b> | Not Done |  |
|  |  |  |                          | ne       |  |

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

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Site No: 1226

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

Subject No: 12262089

Subject Initials: ---

Generated By: (b) (4)

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

5.e Sponsor ID:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.e Test:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.e Result:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.e Not Done:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.e LNMT

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.f

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Sponsor-Defined Identi Not Do | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

**Site No:** 1226

**Subject No:** 12262089

**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>fier:</b>             | ne       |  |
|  |  |  | <b>Test::</b>            | Not Done |  |
|  |  |  |                          | ne       |  |
|  |  |  | <b>Result::</b>          | Not Done |  |
|  |  |  |                          | ne       |  |
|  |  |  | <b>Not Done::</b>        | Not Done |  |
|  |  |  |                          | ne       |  |
|  |  |  | <b>Lab Normal Range:</b> | Not Done |  |
|  |  |  |                          | ne       |  |



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262089

Subject Initials: ---

Generated By: (b) (4)

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

5.f Sponsor ID:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.f Test:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.f Result:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.f Not Done:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.f LNMT

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.g

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Sponsor-Defined Identi Not Do | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

|  |  |  |                          |          |  |
|--|--|--|--------------------------|----------|--|
|  |  |  | <b>fier:</b>             | ne       |  |
|  |  |  | <b>Test::</b>            | Not Done |  |
|  |  |  |                          | ne       |  |
|  |  |  | <b>Result::</b>          | Not Done |  |
|  |  |  |                          | ne       |  |
|  |  |  | <b>Not Done::</b>        | Not Done |  |
|  |  |  |                          | ne       |  |
|  |  |  | <b>Lab Normal Range:</b> | Not Done |  |
|  |  |  |                          | ne       |  |

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262089

Subject Initials: ---

Generated By: (b) (4)

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

5.g Sponsor ID:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.g Test:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.g Result:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.g Not Done:

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.g LNMT

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

5.h

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Sponsor-Defined Identi Not Do | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

|  |  |  |                          |              |  |
|--|--|--|--------------------------|--------------|--|
|  |  |  | <b>fier:</b>             | ne           |  |
|  |  |  | <b>Test::</b>            | Not Do<br>ne |  |
|  |  |  | <b>Result::</b>          | Not Do<br>ne |  |
|  |  |  | <b>Not Done::</b>        | Not Do<br>ne |  |
|  |  |  | <b>Lab Normal Range:</b> | Not Do<br>ne |  |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

**5.h Sponsor ID:**

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.h Test:**

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.h Result:**

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.h Not Done:**

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.h LNMT**

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.i**

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Sponsor-Defined Identi Not Do | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

|  |  |  |                          |          |  |
|--|--|--|--------------------------|----------|--|
|  |  |  | <b>fier:</b>             | ne       |  |
|  |  |  | <b>Test::</b>            | Not Done |  |
|  |  |  |                          | ne       |  |
|  |  |  | <b>Result::</b>          | Not Done |  |
|  |  |  |                          | ne       |  |
|  |  |  | <b>Not Done::</b>        | Not Done |  |
|  |  |  |                          | ne       |  |
|  |  |  | <b>Lab Normal Range:</b> | Not Done |  |
|  |  |  |                          | ne       |  |

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262089

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        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.i Test:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.i Result:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.i Not Done:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.i LNMT**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.j**

| Date                 | Location        | User    | Value              | Reason        |
|----------------------|-----------------|---------|--------------------|---------------|
| Oct-09-2020 16:41:57 | ACV0PFEINFP6000 | (b) (6) | <b>Data Entry:</b> | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

**Site No:** 1226

**Subject No:** 12262089

**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

|                                  |  |                  |   |  |
|----------------------------------|--|------------------|---|--|
| (UTC-03:00) City of Buenos Aires |  | (b) (4), (b) (6) | <b>Sponsor-Defined Identifier:</b> Not Done |  |
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|                                  |  |                  | <b>Result:</b> Not Done                     |  |
|                                  |  |                  | <b>Not Done:</b> Not Done                   |  |
|                                  |  |                  | <b>Lab Normal Range:</b> Not Done           |  |



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

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

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

**5.j Sponsor ID:**

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.j Test:**

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.j Result:**

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.j Not Done:**

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.j LNMT**

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-09-2020 16:41:57 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail  
on Oct/09/2020

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

**Form Status:**

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

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| Date  | Location        | User                | Value        | Reason |
|---|-----------------|---------------------|--------------|--------|
| Oct-09-2020 16:42:25<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Form Created |        |

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Oct/09/2020

Form Version: 15-Sep-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: 12262089

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        |
|--|-----------------|---------------------|----------------------------------|---------------|
| Oct-09-2020 16:42:25<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Oct/9/2020 | Initial Entry |

2.a

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Oct-09-2020 16:42:25<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Record Identifier::</b> 1<br><b>Systolic::</b> 12<br>8<br><b>Diastolic::</b> 82<br><b>Respiratory Rate in respirat ions/minute:</b> 16<br><b>Heart Rate in beats/minute:</b> 56 | Initial Entry |

2.a Record Identifier:

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Oct-09-2020 16:42:25<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>1 | Initial Entry |

2.a Systolic:

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Oct-09-2020 16:42:25<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>128 | Initial Entry |

2.a Diastolic:

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Oct-09-2020 16:42:25<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>82 | Initial Entry |

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History  
on Oct/09/2020

**Form Version:** 15-Sep-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:** 12262089

**Subject Initials:** ---

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

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

**2.a Respiratory Rate in respirations/minute:**

| Date  | Location        | User                | Value                    | Reason        |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-09-2020 16:42:25<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>16 | Initial Entry |

**2.a Heart Rate in beats/minute:**

| Date  | Location        | User                | Value                    | Reason        |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-09-2020 16:42:25<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>56 | Initial Entry |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail  
on Oct/09/2020

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

**Form Status:**

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

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| Date  | Location        | User                | Value        | Reason |
|---|-----------------|---------------------|--------------|--------|
| Oct-09-2020 16:42:38<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Form Created |        |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

**Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**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        |
|--|-----------------|---------------------|----------------------------------|---------------|
| Oct-09-2020 16:42:38<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Oct/9/2020 | Initial Entry |

**2.a**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Oct-09-2020 16:42:38<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Record Identifier::</b> 1<br><b>Oxygen Saturation:</b> 95.0 | Initial Entry |

**2.a Record Identifier:**

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Oct-09-2020 16:42:38<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>1 | Initial Entry |

**2.a SPO2 Pulse Oximetry %**

| Date   | Location        | User                | Value                      | Reason        |
|--|-----------------|---------------------|----------------------------|---------------|
| Oct-09-2020 16:42:38<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>95.0 | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History on Oct/09/2020

**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:** 12262089

**Subject Initials:** ---

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

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

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**1. Date Time of Assessment:**

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Oct-09-2020 16:42:47<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

**2. Arterial Blood Gases PaO2 (mmHg):**

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Oct-09-2020 16:42:47<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

**3. FiO2 (Fraction of Inhaled Oxygen):**

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Oct-09-2020 16:42:47<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1226

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

Subject No: 12262089

Subject Initials: ---

Generated By: (b) (4)

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

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**1. What is the medication identifier?**

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Oct-09-2020 16:42:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

**2. Category:**

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Oct-09-2020 16:42:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

**3. Concomitant Medications Pre-specified:**

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Oct-09-2020 16:42:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

**4. Medication:**

*Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).*

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Oct-09-2020 16:42:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

**5. Start Date:**

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Oct-09-2020 16:42:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Oct/09/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

**6. Ongoing?**

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Oct-09-2020 16:42:59<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** IMAGING - eCRF Audit Trail History  
on Oct/09/2020

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

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**1. Date of Assessment:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Oct-09-2020 16:43:12<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**2. Location of Assessment:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Oct-09-2020 16:43:12<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**3. Type of Imaging Exam:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Oct-09-2020 16:43:12<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**4. Assessment:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Oct-09-2020 16:43:12<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Dec/28/2020

**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:** 12262089

**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   |
|--|-----------------|---------------------------|-----------------------------------|--|
| Dec-29-2020 10:20:31<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted                  | Close Auto Query   |
| Dec-29-2020 10:15:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 2: Deleted                  | Close Auto Query   |
| Dec-29-2020 10:14:28<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 2: Candidate                | Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.          |
| Dec-29-2020 10:14:28<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate                | Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate. |
| Dec-29-2020 10:14:28<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)          | <b>Data Entry:</b><br>Dec/28/2020 | Initial Entry  |

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

| Date   | Location        | User                    | Value                         | Reason        |
|--|-----------------|-------------------------|-------------------------------|---------------|
| Dec-29-2020 10:14:28<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>COVID_B | Initial Entry |

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/28/2020**Form Version:** 10-Dec-2020 02:29**Site No:** 1226**Subject No:** 12262089**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete**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        |
|--|-----------------|------------------|-----------------------------------|---------------|
| Dec-29-2020 10:15:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Dec/28/2020 | Initial Entry |

**2. Date of First Symptom Started:**

| Date   | Location        | User             | Value                             | Reason        |
|--|-----------------|------------------|-----------------------------------|---------------|
| Dec-29-2020 10:15:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Dec/25/2020 | Initial Entry |

**3. Symptoms Ongoing?**

| Date   | Location        | User                | Value   | Reason          |
|--|-----------------|---------------------|---|-----------------|
| Jan-27-2021 15:50:02<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO<br>Date of Last Symptom Resolved:<br>Dec/30/2020 | New Information |
| Dec-29-2020 10:15:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)    | <b>Data Entry:</b><br>YES   | Initial Entry   |

**4.a**

| Date   | Location        | User             | Value  | Reason        |
|--|-----------------|------------------|--|---------------|
| Dec-29-2020 10:15:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptoms:</b> FEVER<br><b>Symptom Present:</b> NO | Initial Entry |

**4.a Symptoms:**

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/28/2020

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1226

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

Subject No: 12262089

Subject Initials: ---

Generated By: (b) (4)

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

|  |                 |                  |                             |               |
|--|-----------------|------------------|-----------------------------|---------------|
| Dec-29-2020 10:15:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>FEVER | Initial Entry |
|--|-----------------|------------------|-----------------------------|---------------|

4.a Was symptom present?

| Date   | Location        | User             | Value                    | Reason        |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-29-2020 10:15:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

4.b

| Date   | Location        | User             | Value   | Reason        |
|--|-----------------|------------------|---|---------------|
| Dec-29-2020 10:15:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Symptoms NEW OR INCREASED COUGH<br>Symptom NO<br>Present: | Initial Entry |

4.b Symptoms:

| Date   | Location        | User             | Value  | Reason        |
|--|-----------------|------------------|--|---------------|
| Dec-29-2020 10:15:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NEW OR INCREASED COUGH | Initial Entry |

4.b Was symptom present?

| Date   | Location        | User             | Value                    | Reason        |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-29-2020 10:15:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

4.c

| Date   | Location        | User             | Value  | Reason        |
|--|-----------------|------------------|--|---------------|
| Dec-29-2020 10:15:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Symptoms NEW OR INCREASED SHORTNESS OF | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/28/2020

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1226

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

Subject No: 12262089

Subject Initials: ---

Generated By: (b) (4)

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

|  |  |  |                               |  |
|--|--|--|-------------------------------|--|
|  |  |  | BREATH<br>Symptom Present: NO |  |
|--|--|--|-------------------------------|--|

4.c Symptoms:

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Dec-29-2020 10:15:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry:<br>NEW OR INCREASED SHORTNESS OF BREATH | Initial Entry |

4.c Was symptom present?

| Date  | Location        | User             | Value             | Reason        |
|---|-----------------|------------------|-------------------|---------------|
| Dec-29-2020 10:15:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry:<br>NO | Initial Entry |

4.d

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Dec-29-2020 10:15:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry:<br>Symptoms: CHILLS<br>Symptom Present: NO | Initial Entry |

4.d Symptoms:

| Date  | Location        | User             | Value                 | Reason        |
|---|-----------------|------------------|-----------------------|---------------|
| Dec-29-2020 10:15:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry:<br>CHILLS | Initial Entry |

4.d Was symptom present?

| Date  | Location        | User             | Value             | Reason        |
|---|-----------------|------------------|-------------------|---------------|
| Dec-29-2020 10:15:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry:<br>NO | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/28/2020

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1226

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

Subject No: 12262089

Subject Initials: ---

Generated By: (b) (4)

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

4.e

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Dec-29-2020 10:15:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Symptom NEW OR INCREASED MUSCLE PAIN<br>Symptom NO<br>Present: | Initial Entry |

4.e Symptoms:

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Dec-29-2020 10:15:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NEW OR INCREASED MUSCLE PAIN | Initial Entry |

4.e Was symptom present?

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Dec-29-2020 10:15:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

4.f

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Dec-29-2020 10:15:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Symptom NEW LOSS OF TASTE OR SMELL<br>Symptom NO<br>Present: | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/28/2020

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1226

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

Subject No: 12262089

Subject Initials: ---

Generated By: (b) (4)

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

4.f Symptoms:

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Dec-29-2020 10:15:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NEW LOSS OF TASTE OR SMELL | Initial Entry |

4.f Was symptom present?

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Dec-29-2020 10:15:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

4.g

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Dec-29-2020 10:15:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Symptom NEW OR INCREASED SORE THROAT<br>Symptom YES<br>Present: | Initial Entry |

4.g Symptoms:

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Dec-29-2020 10:15:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NEW OR INCREASED SORE THROAT | Initial Entry |

4.g Was symptom present?

| Date  | Location        | User             | Value                     | Reason        |
|---|-----------------|------------------|---------------------------|---------------|
| Dec-29-2020 10:15:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

4.h

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)



Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/28/2020

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1226

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

Subject No: 12262089

Subject Initials: ---

Generated By: (b) (4)

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

|  |                 |                  |   |               |
|--|-----------------|------------------|---|---------------|
| Dec-29-2020 10:15:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptoms:</b> DIARRHE<br>A<br><b>Symptom Present</b> NO<br>: | Initial Entry |
|--|-----------------|------------------|---|---------------|

4.h Symptoms:

| Date   | Location        | User             | Value                          | Reason        |
|--|-----------------|------------------|--------------------------------|---------------|
| Dec-29-2020 10:15:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>DIARRHEA | Initial Entry |

4.h Was symptom present?

| Date   | Location        | User             | Value                    | Reason        |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-29-2020 10:15:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

4.i

| Date   | Location        | User             | Value   | Reason        |
|--|-----------------|------------------|---|---------------|
| Dec-29-2020 10:15:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptoms:</b> VOMITIN<br>G<br><b>Symptom Present</b> NO<br>: | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/28/2020

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

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

**Form Status:** Data Complete

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

**4.i Symptoms:**

| Date  | Location        | User             | Value                          | Reason        |
|---|-----------------|------------------|--------------------------------|---------------|
| Dec-29-2020 10:15:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>VOMITING | Initial Entry |

**4.i Was symptom present?**

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Dec-29-2020 10:15:27 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**5.a**

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Dec-29-2020 10:15:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptoms - Other:</b> Coryza | Initial Entry |

**5.a Symptoms - Other Text:**

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Dec-29-2020 10:15:37 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Coryza | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Dec/28/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1226

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

Subject No: 12262089

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        |
|--|-----------------|------------------|--------------------------------|---------------|
| Dec-29-2020 10:15:53<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>Not Done | Initial Entry |

**2. Specimen Type:**

| Date   | Location        | User             | Value                          | Reason        |
|--|-----------------|------------------|--------------------------------|---------------|
| Dec-29-2020 10:15:53<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>Not Done | Initial Entry |

**3. Specimen Collection Location:**

| Date   | Location        | User             | Value                          | Reason        |
|--|-----------------|------------------|--------------------------------|---------------|
| Dec-29-2020 10:15:53<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>Not Done | Initial Entry |

**4. Assay Code and Description:**

| Date   | Location        | User             | Value                          | Reason        |
|--|-----------------|------------------|--------------------------------|---------------|
| Dec-29-2020 10:15:53<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>Not Done | Initial Entry |

**5. Device Type:**

| Date   | Location        | User             | Value                          | Reason        |
|--|-----------------|------------------|--------------------------------|---------------|
| Dec-29-2020 10:15:53<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>Not Done | Initial Entry |

**6. Trade Name:**

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Dec/28/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

|  |                 |                  |                                |               |
|--|-----------------|------------------|--------------------------------|---------------|
| Dec-29-2020 10:15:53<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |
|--|-----------------|------------------|--------------------------------|---------------|

**7. Test Result:**

| Date   | Location        | User             | Value                          | Reason        |
|--|-----------------|------------------|--------------------------------|---------------|
| Dec-29-2020 10:15:53<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**8. Comments/Findings/Details:**

| Date   | Location        | User             | Value                          | Reason        |
|--|-----------------|------------------|--------------------------------|---------------|
| Dec-29-2020 10:15:53<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**9. Trade Name Other, Specify:**

| Date   | Location        | User             | Value                          | Reason        |
|--|-----------------|------------------|--------------------------------|---------------|
| Dec-29-2020 10:15:53<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/28/2020

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

**Site No:** 1226

**Subject No:** 12262089

**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        |
|---|-----------------|----------------------|-------------------------|---------------|
| Dec-29-2020 10:16:12 (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        |
|---|-----------------|----------------------|------------------------------------|---------------|
| Dec-29-2020 10:16:12 (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        |
|---|-----------------|------------------|-----------------------|---------------|
| Dec-29-2020 10:16:12 (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        |
|---|-----------------|------------------|---|---------------|
| Dec-29-2020 10:16:12 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b> Sample was collected on site, recorded at swab pfe | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/28/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1226**Subject No:** 12262089**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[Back to Form](#)**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Dec-29-2020 10:20:31<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Dec-29-2020 10:20:31<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value   | Reason   |
|--|-----------------|---------------------------|---|--|
| Dec-29-2020 10:20:50<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted  | Close Auto Query   |
| Dec-29-2020 10:20:31<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate  | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Dec-29-2020 10:20:31<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>YES<br>Date of Collection:<br>Dec/28/2020 | Initial Entry  |

**5.a**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Dec-29-2020 10:20:50<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BP990J | Initial Entry |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/28/2020

**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:** 12262089

**Subject Initials:** ---

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

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

**5.a Sample ID**

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Dec-29-2020 10:20:50<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>BP990J | Initial Entry |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/28/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

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**1.a**

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Dec-29-2020 10:16:24 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Type of Practitioner:</b> SPECIALIST<br><b>Occurrence of Visits or Contacts:</b> NO | Initial Entry |

**1.a Physician or Healthcare Professional:**

| Date  | Location        | User             | Value                            | Reason        |
|---|-----------------|------------------|----------------------------------|---------------|
| Dec-29-2020 10:16:24 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>SPECIALIST | Initial Entry |

**1.a Occurrence of Visits or Contacts:**

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Dec-29-2020 10:16:24 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**1.b**

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Dec-29-2020 10:16:24 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Type of Practitioner:</b> EMERGENCY ROOM<br><b>Occurrence of Visits or Contacts:</b> NO | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)



Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/28/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen

Site No: 1226

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

Subject No: 12262089

Subject Initials: ---

Generated By: (b) (4)

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

**I.b Physician or Healthcare Professional:**

| Date  | Location        | User             | Value                                | Reason        |
|---|-----------------|------------------|--------------------------------------|---------------|
| Dec-29-2020 10:16:24 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>EMERGENCY ROOM | Initial Entry |

**I.b Occurrence of Visits or Contacts:**

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Dec-29-2020 10:16:24 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**I.c**

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Dec-29-2020 10:16:24 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN<br><b>Occurrence of Visits or Contacts:</b> NO | Initial Entry |

**I.c Physician or Healthcare Professional:**

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Dec-29-2020 10:16:24 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>PRIMARY CARE PHYSICIAN | Initial Entry |

**I.c Occurrence of Visits or Contacts:**

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Dec-29-2020 10:16:24 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**I.d**

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/28/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen

Site No: 1226

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

Subject No: 12262089

Subject Initials: ---

Generated By: (b) (4)

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

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Dec-29-2020 10:16:24 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Type of Practitioner:</b> URGENT CARE<br><b>Occurrence of Visits or Contacts:</b> NO | Initial Entry |

*1.d Physician or Healthcare Professional:*

| Date  | Location        | User             | Value                             | Reason        |
|---|-----------------|------------------|-----------------------------------|---------------|
| Dec-29-2020 10:16:24 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>URGENT CARE | Initial Entry |

*1.d Occurrence of Visits or Contacts:*

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Dec-29-2020 10:16:24 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

*1.e*

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Dec-29-2020 10:16:24 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Type of Practitioner:</b> TELEPHONE CONSULTATION<br><b>Occurrence of Visits or Contacts:</b> NO | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/28/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen

Site No: 1226

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

Subject No: 12262089

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        |
|---|-----------------|------------------|--|---------------|
| Dec-29-2020 10:16:24 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>TELEPHONE CONSULTATION | Initial Entry |

*1.e Occurrence of Visits or Contacts:*

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Dec-29-2020 10:16:24 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

*1.f*

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Dec-29-2020 10:16:24 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Type of Practitioner:</b> OTHER<br><b>Occurrence of Visits or Contacts:</b> NO | Initial Entry |

*1.f Physician or Healthcare Professional:*

| Date  | Location        | User             | Value                       | Reason        |
|---|-----------------|------------------|-----------------------------|---------------|
| Dec-29-2020 10:16:24 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>OTHER | Initial Entry |

*1.f Occurrence of Visits or Contacts:*

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Dec-29-2020 10:16:24 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/28/2020

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

**Form Status:** Data Complete, Frozen

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

|   |                 |                  |                          |               |
|---|-----------------|------------------|--------------------------|---------------|
| Dec-29-2020 10:16:24<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |
|---|-----------------|------------------|--------------------------|---------------|

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History  
on Dec/28/2020

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

**Form Status:** Data Complete

**Site No:** 1226

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

**Subject No:** 12262089

**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        |
|---|-----------------|-------------------------|--|---------------|
| Dec-29-2020 10:16:35<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>POTENTIAL COVID-19 ILLNES<br>S | Initial Entry |

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

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Dec-29-2020 10:16:35<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**3. Toxicity Grade:**

| Date  | Location        | User             | Value                   | Reason        |
|---|-----------------|------------------|-------------------------|---------------|
| Dec-29-2020 10:16:35<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>1 | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail  
on Dec/28/2020

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

**Form Status:**

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

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| Date  | Location        | User             | Value        | Reason |
|---|-----------------|------------------|--------------|--------|
| Dec-29-2020 10:17:30<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created |        |

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Dec/28/2020

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete

Site No: 1226

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

Subject No: 12262089

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        |
|---|-----------------|------------------|----------------------------|---------------|
| Dec-29-2020 10:17:30 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry:<br>Dec/28/2020 | Initial Entry |

2.a

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Dec-29-2020 10:17:30 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry:<br>Record Identifier:: 1<br>Systolic:: 13<br>Diastolic:: 77<br>Respiratory Rate in respirations/minute: 16<br>Heart Rate in beats/minute: 76 | Initial Entry |

2.a Record Identifier:

| Date  | Location        | User             | Value            | Reason        |
|---|-----------------|------------------|------------------|---------------|
| Dec-29-2020 10:17:30 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry:<br>1 | Initial Entry |

2.a Systolic:

| Date  | Location        | User             | Value              | Reason        |
|---|-----------------|------------------|--------------------|---------------|
| Dec-29-2020 10:17:30 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry:<br>131 | Initial Entry |

2.a Diastolic:

| Date  | Location        | User             | Value             | Reason        |
|---|-----------------|------------------|-------------------|---------------|
| Dec-29-2020 10:17:30 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry:<br>77 | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History  
on Dec/28/2020

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

**Form Status:** Data Complete

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

|              |  |  |  |  |
|--------------|--|--|--|--|
| Buenos Aires |  |  |  |  |
|--------------|--|--|--|--|

**2.a Respiratory Rate in respirations/minute:**

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Dec-29-2020 10:17:30<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>16 | Initial Entry |

**2.a Heart Rate in beats/minute:**

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Dec-29-2020 10:17:30<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>76 | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail  
on Dec/28/2020

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

**Form Status:**

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

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| Date  | Location        | User             | Value        | Reason |
|---|-----------------|------------------|--------------|--------|
| Dec-29-2020 10:17:44<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created |        |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/28/2020

**Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

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

**Form Status:** Data Complete

**Site No:** 1226

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

**Subject No:** 12262089

**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        |
|---|-----------------|------------------|-----------------------------------|---------------|
| Dec-29-2020 10:17:44 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Dec/28/2020 | Initial Entry |

**2.a**

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Dec-29-2020 10:17:44 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Record Identifier::</b> 1<br><b>Oxygen Saturation:</b> 99.0 | Initial Entry |

**2.a Record Identifier:**

| Date  | Location        | User             | Value                   | Reason        |
|---|-----------------|------------------|-------------------------|---------------|
| Dec-29-2020 10:17:44 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>1 | Initial Entry |

**2.a SPO2 Pulse Oximetry %**

| Date  | Location        | User             | Value                      | Reason        |
|---|-----------------|------------------|----------------------------|---------------|
| Dec-29-2020 10:17:44 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>99.0 | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_CONVA 1 - Unscheduled Visit on Nov/06/2020**Form Version:** 22-Apr-2020 21:04**Site No:** 1226**Subject No:** 12262089**Generated By:** (b) (4)**Form:** DATE OF VISIT - ILLNESS CONVALESCENT - 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 Visit**

| Date  | Location                                  | User                 | Value                                | Reason   |
|---|---|----------------------|--------------------------------------|--|
| Nov-10-2020<br>02:56:27<br>(UTC-03:00)<br>City of<br>Buenos Aires | ACV0PFEINFP6000                           | (b) (4), (b) (6)     | Query 1<br>: Closed                  | Closed as per site response.   |
| Nov-09-2020<br>07:50:29<br>(UTC-03:00)<br>City of<br>Buenos Aires | ACV0PFEINFP6000                           | (b) (4), (b) (6)     | Query 1<br>: Answered                | Both visits happened on the same day.  |
| Nov-09-2020<br>05:31:31<br>(UTC-03:00)<br>City of<br>Buenos Aires | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY<br>(b) (4) | Query 1<br>: Opened                  | DMW5308174;The Date of Visit at Visit COVID_A1 is the same as the other Date of Visit at Visit V2_VAX2_L. Please review for duplication and update as appropriate. |
| Nov-06-2020<br>16:46:35<br>(UTC-03:00)<br>City of<br>Buenos Aires | ACV0PFEINFP6000                           | (b) (4), (b) (6)     | <b>Data Entry:</b><br>Nov/6/<br>2020 | Initial Entry  |

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

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-06-2020 16:46:35<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>COVID_A1 | Initial Entry |

**Header Text:** C4591001**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Nov/06/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1226**Subject No:** 12262089**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        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Nov-07-2020 08:56:37<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                       | Reason        |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Nov-07-2020 08:56:37<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                      | Value  | Reason  |
|---|-----------------|---------------------------|--|---|
| Nov-07-2020 08:56:45<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted   | Close Auto Query  |
| Nov-07-2020 08:56:37<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate   | 'Sample Collected?'<br>is Yes, however no<br>barcodes are<br>entered. Please<br>review and correct<br>as appropriate. |
| Nov-07-2020 08:56:37<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Nov/6/2020 | Initial Entry   |

**5.a**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Nov-07-2020 08:56:45<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BR691S | Initial Entry |

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Nov/06/2020

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

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

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

**Site No:** 1226

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

**Subject No:** 12262089

**Subject Initials:** ---

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

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

|  |  |                  |  |  |
|--|--|------------------|--|--|
|  |  | (b) (4), (b) (6) |  |  |
|--|--|------------------|--|--|

**5.a Sample ID**

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Nov-07-2020 08:56:45<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BR691S | Initial Entry |

**5.b**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Nov-07-2020 08:56:52<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BS2XCB | Initial Entry |

**5.b Sample ID**

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Nov-07-2020 08:56:52<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BS2XCB | Initial Entry |

**5.c**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Nov-07-2020 08:56:58<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BS2XCC | Initial Entry |

**5.c Sample ID**

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Nov-07-2020 08:56:58<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BS2XCC | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 2 - Unscheduled  
Visit on Jan/27/2021

**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:** 12262089

**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-27-2021 15:50:44<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Jan/27/2021 | Initial Entry |

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

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-27-2021 15:50:44<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>COVID_B1 | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_CONVA 2 - Unscheduled Visit on Jan/27/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1226**Subject No:** 12262089**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-28-2021 08:11:40<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                       | Reason        |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Jan-28-2021 08:11:40<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value   | Reason   |
|--|-----------------|---------------------------|---|--|
| Jan-28-2021 08:11:49<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted  | Close Auto Query   |
| Jan-28-2021 08:11:40<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate  | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Jan-28-2021 08:11:40<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Jan/27/2021 | Initial Entry  |

**5.a**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Jan-28-2021 08:11:49<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BRH0HD | Initial Entry |

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 2 - Unscheduled  
Visit on Jan/27/2021

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

**Site No:** 1226

**Subject No:** 12262089

**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.a Sample ID**

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Jan-28-2021 08:11:49<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>BRH0HD | Initial Entry |

**5.b**

| Date  | Location        | User                | Value                                   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Jan-28-2021 08:11:57<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>Sample ID: BSF3ZM | Initial Entry |

**5.b Sample ID**

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Jan-28-2021 08:11:57<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>BSF3ZM | Initial Entry |

**5.c**

| Date  | Location        | User                | Value                                   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Jan-28-2021 08:12:05<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>Sample ID: BSF3ZN | Initial Entry |

**5.c Sample ID**

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Jan-28-2021 08:12:05<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>BSF3ZN | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)



**Header Text:** C4591001

**Visit:** End of Treatment - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262089

**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        |
|--|-----------------|------------------|-----------------------------------|---------------|
| Dec-10-2020 16:50:52<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Dec/10/2020 | Initial Entry |

**2. Phase of Disposition:**

| Date   | Location        | User                    | Value                             | Reason        |
|--|-----------------|-------------------------|-----------------------------------|---------------|
| Dec-10-2020 16:50:52<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>VACCINATION | Initial Entry |

**3. Status:**

| Date   | Location        | User                | Value                           | Reason   |
|--|-----------------|---------------------|---------------------------------|--|
| Dec-14-2020 11:28:07<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)    | Query 1: Closed                 | wrong query, soory                                   |
| Dec-14-2020 07:39:18<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Answered               | Sorry, we do not understand why we need to complete. |
| Dec-11-2020 12:10:35<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)    | Query 1: Opened                 | CLIN: Pls complete the follow up page                |
| Dec-10-2020 16:50:52<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)    | <b>Data Entry:</b><br>COMPLETED | Initial Entry  |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262089

**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        |
|---|-----------------|--------------------------------|----------------------------------|---------------|
| Feb-17-2021 15:31:34<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>[Redacted] | <b>Data Entry:</b><br>Feb/8/2021 | Initial Entry |

**Header Text:** C4591001

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

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

**Site No:** 1226

**Subject No:** 12262089

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

**Form:** FURTHER VACCINATION CONFIRMATION - 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. Select appropriate response - Is participant willing to return for Vaccination 3?*

| Date  | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Feb-17-2021 15:31:42<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Participant is willing to return fo<br>r Vaccination 3<br>Participant is:<br><br>eligible and NOT confirmed t<br>o have received only placebo<br>at Vaccination 1/2 | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262089

**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-06-2020 16:45:04<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Form Created |        |

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262089

**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 |
|---|-----------------|--------------------------------|--------------|--------|
| Dec-10-2020 16:54:11<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>[Redacted] | Form Created |        |

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262089

**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 |
|---|-----------------|------------------|--------------|--------|
| Dec-10-2020 16:55:13<br>(UTC-03:00) City of<br>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:** 12262089

**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 |
|---|-----------------|------------------|--------------|--------|
| Dec-10-2020 16:55:41<br>(UTC-03:00) City of<br>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:** 12262089

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

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**Subject Initials:** ---

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| Date  | Location        | User             | Value        | Reason |
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| Dec-10-2020 16:56:09<br>(UTC-03:00) City of<br>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:** 12262089

**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 |
|---|-----------------|------------------|--------------|--------|
| Dec-10-2020 16:56:38<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created |        |

Header Text: C4591001

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Site No: 1226

Subject No: 12262089

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: ---

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**1. Category:**

| Date   | Location        | User                    | Value                               | Reason        |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Nov-06-2020 16:45:04<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ADVERSE EVENT | Initial Entry |

**2. AE ID:**

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Nov-06-2020 16:45:04<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>1 | Initial Entry |

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-06-2020 16:45:04<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Urinary tract infection | Initial Entry |

**4. Start Date Time:**

| Date   | Location        | User                      | Value                                   | Reason                                 |
|--|-----------------|---------------------------|---|--|
| Nov-12-2020 17:02:28<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)          | <b>Data Entry:</b><br>Oct/18/2020 06:00 | New Information                        |
| Nov-12-2020 09:01:45<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)          | Query 1: Closed                         | Response satisfies query               |
| Nov-11-2020 14:51:16<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Answered                       | New Information                        |
| Nov-11-2020 14:51:16<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)          | <b>Data Entry:</b><br>Oct/20/2020 06:00 | New Information                        |
| Nov-11-2020 08:53:04<br>(UTC-03:00) City of              | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Reissued:Opened                | SAE RECON 1: Per narrative of the case |

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**Subject No:** 12262089

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

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|   |                 |                  |   |  |
|---|-----------------|------------------|---|--|
| Buenos Aires  |                 | (b) (4)          |   | a follow up on 10Nov2020 indicates (onset updated to 20Oct2020), additional reporter, anatomical location of administration and lab data details. Please confirm correct onset date and update accordingly.                      |
| Nov-10-2020 09:46:46 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Candidate             | Pending SDB update   |
| Nov-09-2020 12:29:22 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered                       | The Follow-up SAE Form 1 of 07NOV2020 corrected the onset date from 20OCT2020 to 18OCT2020.  |
| Nov-09-2020 07:20:47 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened                         | SAE RECON: AER#2020437602 ,onset date was updated to 18Oct2020 in AE CRF however, recorded as 20Oct2020 on Safety database. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form. |
| Nov-07-2020 13:02:01 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Oct/18/2020 06:00 | New Information  |
| Nov-06-2020 16:46:20 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Oct/20/2020 06:00 | New Information  |

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|  |                 |                  |   |               |
|--|-----------------|------------------|---|---------------|
| Nov-06-2020 16:45:04<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Oct/20/2020 UNK:UNK | Initial Entry |
|--|-----------------|------------------|---|---------------|

5. Is the adverse event still ongoing?

| Date   | Location        | User             | Value   | Reason        |
|--|-----------------|------------------|---|---------------|
| Nov-06-2020 16:45:04<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO<br>End Date Time:<br><br>Oct/22/2020 UNK:UNK | Initial Entry |

6. Toxicity Grade:

| Date   | Location        | User             | Value                   | Reason        |
|--|-----------------|------------------|-------------------------|---------------|
| Nov-06-2020 16:45:04<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>3 | Initial Entry |

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

| Date   | Location        | User                      | Value                     | Reason  |
|--|-----------------|---------------------------|---------------------------|---|
| Nov-07-2020 11:52:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted          | Close Auto Query  |
| Nov-06-2020 16:45:04<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate        | For AE Urinary tract infection: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank. |
| Nov-06-2020 16:45:04<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (6)                   | <b>Data Entry:</b><br>YES | Initial Entry   |

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**Subject No:** 12262089

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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**Subject Initials:** ---

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

|              |  |                  |   |
|--------------|--|------------------|---|
| Buenos Aires |  | (b) (4), (b) (6) | <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> |
|--------------|--|------------------|---|

**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-06-2020 16:45:04 (UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**9. Is this event related to study treatment:**

| Date                 | Location        | User    | Value              | Reason        |
|----------------------|-----------------|---------|--------------------|---------------|
| Nov-06-2020 16:45:04 | ACV0PFEINFP6000 | (b) (6) | <b>Data Entry:</b> | Initial Entry |

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Generated By: (b) (4)

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|                                  |  |                  |   |  |
|----------------------------------|--|------------------|---|--|
| (UTC-03:00) City of Buenos Aires |  | (b) (4), (b) (6) | NOT RELATED<br>If Not Related to study treatment (s), this event is due to:<br><br>OTHER<br><br>If Other, specify:<br><br>urinary infection |  |
|----------------------------------|--|------------------|---|--|

10. Latest Action Taken with Study Treatment:

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-06-2020 16:45:04<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Nov-06-2020 16:45:04<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-06-2020 16:45:04<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

13. What was the outcome of this adverse event?:

| Date   | Location        | User                | Value                                    | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-06-2020 16:45:04<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>RECOVERED/RESOLVED | Initial Entry |

14. Did the adverse event cause the subject to be discontinued from the study?

| Date                 | Location        | User    | Value              | Reason        |
|----------------------|-----------------|---------|--------------------|---------------|
| Nov-06-2020 16:45:04 | ACV0PFEINFP6000 | (b) (6) | <b>Data Entry:</b> | Initial Entry |

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**Site No:** 1226

**Subject No:** 12262089

**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

|                                  |  |                  |    |  |
|----------------------------------|--|------------------|----|--|
| (UTC-03:00) City of Buenos Aires |  | (b) (4), (b) (6) | NO |  |
|----------------------------------|--|------------------|----|--|

**15. Serious Adverse Event Number: For Pfizer Use Only**

| Date   | Location        | User                | Value                            | Reason        |
|--|-----------------|---------------------|----------------------------------|---------------|
| Nov-07-2020 11:52:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>2020437602 | Initial Entry |

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262089

**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        |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Dec-10-2020 16:54:11<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ADVERSE EVENT | Initial Entry |

**2. AE ID:**

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Dec-10-2020 16:54:11<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>2 | Initial Entry |

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

| Date   | Location        | User             | Value  | Reason        |
|--|-----------------|------------------|--|---------------|
| Dec-10-2020 16:54:11<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Pain at injection site | Initial Entry |

**4. Start Date Time:**

| Date   | Location        | User             | Value                                  | Reason        |
|--|-----------------|------------------|--|---------------|
| Dec-10-2020 16:54:11<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Nov/6/2020 21:00 | Initial Entry |

**5. Is the adverse event still ongoing?**

| Date   | Location        | User             | Value  | Reason        |
|--|-----------------|------------------|--|---------------|
| Dec-10-2020 16:54:11<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO<br>End Date Time:<br><br>Nov/7/2020 UNK:UNK | Initial Entry |

**6. Toxicity Grade:**

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Header Text: C4591001

Visit: Logs - Unscheduled

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Site No: 1226

Subject No: 12262089

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        |
|--|-----------------|------------------|-------------------------|---------------|
| Dec-10-2020 16:54:11<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>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        |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-10-2020 16:54:11<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

| Date   | Location        | User             | Value                    | Reason        |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-10-2020 16:54:11<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

9. Is this event related to study treatment:

| Date   | Location        | User             | Value                         | Reason        |
|--|-----------------|------------------|-------------------------------|---------------|
| Dec-10-2020 16:54:11<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>RELATED | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date   | Location        | User             | Value                                | Reason        |
|--|-----------------|------------------|--------------------------------------|---------------|
| Dec-10-2020 16:54:11<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

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**Header Text:** C4591001

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

**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

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| Date   | Location        | User             | Value                     | Reason        |
|--|-----------------|------------------|---------------------------|---------------|
| Dec-10-2020 16:54:11<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

**12. Was a Non-Drug Treatment given?**

| Date   | Location        | User             | Value                    | Reason        |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-10-2020 16:54:11<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**13. What was the outcome of this adverse event?:**

| Date   | Location        | User             | Value                                    | Reason        |
|--|-----------------|------------------|--|---------------|
| Dec-10-2020 16:54:11<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>RECOVERED/RESOLVED | Initial Entry |

**14. Did the adverse event cause the subject to be discontinued from the study?**

| Date   | Location        | User             | Value                    | Reason        |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-10-2020 16:54:11<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

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**Subject Initials:** ---

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**1. Category:**

| Date   | Location        | User                    | Value                               | Reason        |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Dec-10-2020 16:55:13<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ADVERSE EVENT | Initial Entry |

**2. AE ID:**

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Dec-10-2020 16:55:13<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>3 | Initial Entry |

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

| Date   | Location        | User             | Value                         | Reason        |
|--|-----------------|------------------|-------------------------------|---------------|
| Dec-10-2020 16:55:13<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Malaise | Initial Entry |

**4. Start Date Time:**

| Date   | Location        | User             | Value                                  | Reason        |
|--|-----------------|------------------|--|---------------|
| Dec-10-2020 16:55:13<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Nov/6/2020 21:00 | Initial Entry |

**5. Is the adverse event still ongoing?**

| Date   | Location        | User             | Value  | Reason        |
|--|-----------------|------------------|--|---------------|
| Dec-10-2020 16:55:13<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO<br>End Date Time:<br><br>Nov/6/2020 UNK:UNK | Initial Entry |

**6. Toxicity Grade:**

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| Date   | Location        | User             | Value                   | Reason        |
|--|-----------------|------------------|-------------------------|---------------|
| Dec-10-2020 16:55:13<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>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        |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-10-2020 16:55:13<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

| Date   | Location        | User             | Value                    | Reason        |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-10-2020 16:55:13<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

9. Is this event related to study treatment:

| Date   | Location        | User             | Value                         | Reason        |
|--|-----------------|------------------|-------------------------------|---------------|
| Dec-10-2020 16:55:13<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>RELATED | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date   | Location        | User             | Value                                | Reason        |
|--|-----------------|------------------|--------------------------------------|---------------|
| Dec-10-2020 16:55:13<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262089

**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        |
|--|-----------------|------------------|---------------------------|---------------|
| Dec-10-2020 16:55:13<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

**12. Was a Non-Drug Treatment given?**

| Date   | Location        | User             | Value                    | Reason        |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-10-2020 16:55:13<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**13. What was the outcome of this adverse event?:**

| Date   | Location        | User             | Value                                    | Reason        |
|--|-----------------|------------------|--|---------------|
| Dec-10-2020 16:55:13<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>RECOVERED/RESOLVED | Initial Entry |

**14. Did the adverse event cause the subject to be discontinued from the study?**

| Date   | Location        | User             | Value                    | Reason        |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-10-2020 16:55:13<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262089

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        |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Dec-10-2020 16:55:41<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ADVERSE EVENT | Initial Entry |

**2. AE ID:**

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Dec-10-2020 16:55:41<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>4 | Initial Entry |

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

| Date   | Location        | User             | Value                        | Reason        |
|--|-----------------|------------------|------------------------------|---------------|
| Dec-10-2020 16:55:41<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Chills | Initial Entry |

**4. Start Date Time:**

| Date   | Location        | User             | Value                                  | Reason        |
|--|-----------------|------------------|--|---------------|
| Dec-10-2020 16:55:41<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Nov/6/2020 21:00 | Initial Entry |

**5. Is the adverse event still ongoing?**

| Date   | Location        | User             | Value  | Reason        |
|--|-----------------|------------------|--|---------------|
| Dec-10-2020 16:55:41<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO<br>End Date Time:<br><br>Nov/6/2020 UNK:UNK | Initial Entry |

**6. Toxicity Grade:**

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262089

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        |
|--|-----------------|------------------|-------------------------|---------------|
| Dec-10-2020 16:55:41<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>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        |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-10-2020 16:55:41<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**8. Is this adverse event the result of a study Medication Error?**

**If Yes, record the type of medication error on the Medication Error Log.**

| Date   | Location        | User             | Value                    | Reason        |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-10-2020 16:55:41<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**9. Is this event related to study treatment:**

| Date   | Location        | User             | Value                         | Reason        |
|--|-----------------|------------------|-------------------------------|---------------|
| Dec-10-2020 16:55:41<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>RELATED | Initial Entry |

**10. Latest Action Taken with Study Treatment:**

| Date   | Location        | User             | Value                                | Reason        |
|--|-----------------|------------------|--------------------------------------|---------------|
| Dec-10-2020 16:55:41<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NOT APPLICABLE | Initial Entry |

**11. Was a Concomitant Medication given?**

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262089

**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        |
|--|-----------------|------------------|---------------------------|---------------|
| Dec-10-2020 16:55:41<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

**12. Was a Non-Drug Treatment given?**

| Date   | Location        | User             | Value                    | Reason        |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-10-2020 16:55:41<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**13. What was the outcome of this adverse event?:**

| Date   | Location        | User             | Value                                    | Reason        |
|--|-----------------|------------------|--|---------------|
| Dec-10-2020 16:55:41<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>RECOVERED/RESOLVED | Initial Entry |

**14. Did the adverse event cause the subject to be discontinued from the study?**

| Date   | Location        | User             | Value                    | Reason        |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-10-2020 16:55:41<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)



Header Text: C4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262089

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        |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Dec-10-2020 16:56:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ADVERSE EVENT | Initial Entry |

**2. AE ID:**

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Dec-10-2020 16:56:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>5 | Initial Entry |

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

| Date   | Location        | User             | Value                             | Reason        |
|--|-----------------|------------------|-----------------------------------|---------------|
| Dec-10-2020 16:56:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Muscle pain | Initial Entry |

**4. Start Date Time:**

| Date   | Location        | User             | Value                                  | Reason        |
|--|-----------------|------------------|--|---------------|
| Dec-10-2020 16:56:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Nov/6/2020 21:00 | Initial Entry |

**5. Is the adverse event still ongoing?**

| Date   | Location        | User             | Value  | Reason        |
|--|-----------------|------------------|--|---------------|
| Dec-10-2020 16:56:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO<br>End Date Time:<br><br>Nov/6/2020 UNK:UNK | Initial Entry |

**6. Toxicity Grade:**

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262089

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        |
|--|-----------------|------------------|-------------------------|---------------|
| Dec-10-2020 16:56:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>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        |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-10-2020 16:56:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

| Date   | Location        | User             | Value                    | Reason        |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-10-2020 16:56:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

9. Is this event related to study treatment:

| Date   | Location        | User             | Value                         | Reason        |
|--|-----------------|------------------|-------------------------------|---------------|
| Dec-10-2020 16:56:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>RELATED | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date   | Location        | User             | Value                                | Reason        |
|--|-----------------|------------------|--------------------------------------|---------------|
| Dec-10-2020 16:56:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262089

**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        |
|--|-----------------|------------------|---------------------------|---------------|
| Dec-10-2020 16:56:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

**12. Was a Non-Drug Treatment given?**

| Date   | Location        | User             | Value                    | Reason        |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-10-2020 16:56:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**13. What was the outcome of this adverse event?:**

| Date   | Location        | User             | Value                                    | Reason        |
|--|-----------------|------------------|--|---------------|
| Dec-10-2020 16:56:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>RECOVERED/RESOLVED | Initial Entry |

**14. Did the adverse event cause the subject to be discontinued from the study?**

| Date   | Location        | User             | Value                    | Reason        |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-10-2020 16:56:09<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262089

**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        |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Dec-10-2020 16:56:38<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ADVERSE EVENT | Initial Entry |

**2. AE ID:**

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Dec-10-2020 16:56:38<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>6 | Initial Entry |

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

| Date   | Location        | User                | Value                    | Reason   |
|--|-----------------|---------------------|--------------------------|--|
| Dec-15-2020 10:11:27<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)    | Query 1: Closed          | PD will be sent  |
| Dec-14-2020 13:52:14<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Answered        | The PI related this symptom to vaccine reactogenicity, because it happens less than seven days after the vaccination. So, a Covid Illness is not necessary according his evaluation. |
| Dec-14-2020 12:24:40<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6)    | Query 1: Reissued:Opened | Clin: Although related, pls move nausea to COVID CRF, thanks   |
| Dec-14-2020 11:46:46<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Answered        | This event is related with vaccine reactogenicity.   |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262089

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

|  |                 |                  |                              |                              |
|--|-----------------|------------------|------------------------------|------------------------------|
| Dec-14-2020 11:25:43<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened              | pls move nausea to COVID CRF |
| Dec-10-2020 16:56:38<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Nausea | Initial Entry                |

4. Start Date Time:

| Date   | Location        | User             | Value                                  | Reason        |
|--|-----------------|------------------|--|---------------|
| Dec-10-2020 16:56:38<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Nov/6/2020 21:00 | Initial Entry |

5. Is the adverse event still ongoing?

| Date   | Location        | User             | Value  | Reason        |
|--|-----------------|------------------|--|---------------|
| Dec-10-2020 16:56:38<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO<br>End Date Time:<br>Nov/6/2020 UNK:UNK | Initial Entry |

6. Toxicity Grade:

| Date   | Location        | User             | Value                   | Reason        |
|--|-----------------|------------------|-------------------------|---------------|
| Dec-10-2020 16:56:38<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>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        |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-10-2020 16:56:38<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

Header Text: C4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12262089

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

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

| Date   | Location        | User             | Value                    | Reason        |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-10-2020 16:56:38<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>NO | Initial Entry |

9. Is this event related to study treatment:

| Date   | Location        | User             | Value                         | Reason        |
|--|-----------------|------------------|-------------------------------|---------------|
| Dec-10-2020 16:56:38<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>RELATED | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date   | Location        | User             | Value                                | Reason        |
|--|-----------------|------------------|--------------------------------------|---------------|
| Dec-10-2020 16:56:38<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

| Date   | Location        | User             | Value                     | Reason        |
|--|-----------------|------------------|---------------------------|---------------|
| Dec-10-2020 16:56:38<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>YES | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date   | Location        | User             | Value                    | Reason        |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-10-2020 16:56:38<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>NO | Initial Entry |

13. What was the outcome of this adverse event?:

| Date   | Location        | User             | Value                                    | Reason        |
|--|-----------------|------------------|--|---------------|
| Dec-10-2020 16:56:38<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>RECOVERED/RESOLVED | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262089

**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

**14. Did the adverse event cause the subject to be discontinued from the study?**

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Dec-10-2020 16:56:38<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u><br>NO | Initial Entry |

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262089

**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-17-2021 15:31:24<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Feb/9/2021 | Initial Entry |

**2. Primary Reason for Unblinding:**

| Date   | Location        | User             | Value   | Reason        |
|--|-----------------|------------------|---|---------------|
| Feb-17-2021 15:31:24<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION | Initial Entry |



**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262089

**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        |
|--|-----------------|-------------------------|---|---------------|
| Dec-10-2020 16:50:52<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>FOLLOW-UP           | Initial Entry |
| Oct-06-2020 13:24:01<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ENROLLED/RANDOMIZED | Initial Entry |
| Oct-06-2020 13:20:51<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SCREENED            | Initial Entry |

**2. Subject Status Date**

| Date   | Location        | User                    | Value                             | Reason        |
|--|-----------------|-------------------------|-----------------------------------|---------------|
| Dec-10-2020 16:50:52<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Dec/10/2020 | Initial Entry |
| Oct-06-2020 13:24:01<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Oct/6/2020  | Initial Entry |
| Oct-06-2020 13:20:51<br>(UTC-03:00) City of Buenos Aires | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Oct/6/2020  | Initial Entry |

090177e196ae4061\Final\Final On: 01-Apr-2021 05:38 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1226

**Subject No:** 12262089

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

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

**Form Status:** Data Complete, Signed, 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. Casebook Signature*

| Date  | Location        | User                | Value                                      | Reason        |
|---|-----------------|---------------------|--|---------------|
| Nov-13-2020 09:01:27<br>(UTC-03:00) City of<br>Buenos Aires | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Click Here to Enable | Initial Entry |