

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** COHORT\_SELECTION

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[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:** 1217

**Subject No:** 12171044

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

**Form:** MAIN INFORMED CONSENT

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Informed Consent**

|    |              |   |
|----|--------------|---|
| 1. | Consent Was: | OBTAINED<br>Date Written Consent Obtained<br>Nov/4/2020 |
|----|--------------|---|

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Demography**

|    |                                 |  |
|----|---------------------------------|--|
| 1. | Subject ID                      | [12171044]                                     |
| 2. | Birth Date:                     | (b) (6)/1985                                   |
| 3. | Sex:                            | MALE   |
| 4. | Ethnicity:                      | NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN |
| 5. | Race: (Check X all that apply): | WHITE  |
| 6. | Racial Designation:             |  |

**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** DATE OF VISIT

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |            |
|----|-----------------|------------|
| 1. | Date of Visit   | Nov/4/2020 |
| 2. | Erroneous Visit |            |

**Header Text:** C4591001

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

**Form Version:** 10-Oct-2020 16:00

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

Form Comments

**Inclusion Criteria Not Met**

|    |   |                |
|----|---|----------------|
| 1. | Description of Inclusion Criterion<br>Not Met | Not Applicable |
|----|---|----------------|

**Exclusion Criteria Met**

|    |   |                |
|----|---|----------------|
| 2. | Description of Exclusion Criterion<br>Met | Not Applicable |
|----|---|----------------|

**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Disposition - Screening**

|    |   |            |
|----|---|------------|
| 1. | Date of Completion/Discontinuation /Death | Nov/4/2020 |
| 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:** 1217

**Subject No:** 12171044

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**Form Comments**

**Medical History Details**

|    |   |                               |
|----|---|-------------------------------|
| 1. | Line/MH Number:   | Not Applicable<br>_____       |
|    | Disease/Syndrome/Surgery<br>/Non-Drug Allergies/Drug Allergies: | Not Applicable<br>_____       |
|    | Start Date:   | Not Applicable<br>_____<br>// |
|    | Ongoing:  | Not Applicable<br>_____       |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** HIV STATUS

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[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:** 10-Oct-2020 16:04

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Vital Signs**

|    |                  |            |
|----|------------------|------------|
| 1. | Date:            | Nov/4/2020 |
| 2. | Weight:          | [97.0]     |
| 3. | Unit:            | kg         |
| 4. | Height:          | [185.0]    |
| 5. | Unit:            | cm         |
| 6. | Body Mass Index: | [28.3]     |

**Vital Signs Details**

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

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**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** RANDOMIZATION

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Disposition**

|    |                       |            |
|----|-----------------------|------------|
| 1. | Randomization Date :  | Nov/4/2020 |
| 2. | Randomization Number: | [115479]   |
| 3. | Randomization Group:  | [ ]        |

**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |  |
|----|--|--|
| 1. | Data Origin  | SITE                                     |
| 2. | Sample Type  | SERUM                                    |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Nov/4/2020 |
| 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 | [BPZ97B] |
| 5.b | Sample ID | [BPZ97C] |
| 5.c | Sample ID | [BS2S65] |
| 5.d | Sample ID | [BS2S66] |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171044

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

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

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**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/4/2020 |
| 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 | [BPZ978] |
|-----|-----------|----------|

**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** VACCINATION

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**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/4/2020 14:20                          |
| 5.  | Anatomical Location:  | DELTOID MUSCLE                            |
| 6.  | Body Side:  | LEFT                                      |
| 7.  | Route:  | INTRAMUSCULAR                             |
| 8.  | Actual Dose:  | [ ]                                       |
| 9.  | Unit:   |   |
| 10. | Timeframe Subject Was Observed  | THE PROTOCOL SPECIFIED OBSERVATION PERIOD |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES                                       |

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**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

|    |  |   |
|----|--|---|
| 1. | Select appropriate response -<br>Reactogenicity diary collection | YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT |
|----|--|---|

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** DATE OF VISIT

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Dec/10/2020 |
| 2. | Erroneous Visit |             |

Header Text: C4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

|     |   |  |
|-----|---|--|
| 1.  | Were medications to treat fever/pain given on the last day the Subject Diary was completed? | NO   |
| 2.a | Symptom:  | FEVER  |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO   |
| 2.b | Symptom:  | FATIGUE  |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | YES<br>Ongoing?<br>YES                             |
| 2.c | Symptom:  | HEADACHE   |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO   |
| 2.d | Symptom:  | CHILLS   |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | YES<br>Ongoing?<br>NO<br>Stop Date:<br>Dec/10/2020 |
| 2.e | Symptom:  | VOMITING   |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO   |
| 2.f | Symptom:  | DIARRHEA   |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | NO   |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)



**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 10-Oct-2020 16:03

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

|     |  |  |
|-----|--|--|
| 2.g | Symptom:   | NEW OR WORSENERED MUSCLE PAIN                      |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | YES<br>Ongoing?<br>NO<br>Stop Date:<br>Dec/10/2020 |
| 2.h | Symptom:   | NEW OR WORSENERED JOINT PAIN                       |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO   |
| 3.  | Injection Site Location:   | DELTOID MUSCLE                                     |
| 4.  | Injection Site Body Side:  | LEFT   |
| 5.a | Injection Site Reaction:   | REDNESS  |
|     | Were injection site reactions present on the last day the Subject Diary was completed?   | NO   |
| 5.b | Injection Site Reaction:   | SWELLING   |
|     | Were injection site reactions present on the last day the Subject Diary was completed?   | NO   |
| 5.c | Injection Site Reaction:   | PAIN AT INJECTION SITE                             |
|     | Were injection site reactions present on the last day the Subject Diary was completed?   | NO   |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:27

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Vital Signs**

|    |       |             |
|----|-------|-------------|
| 1. | Date: | Dec/10/2020 |
|----|-------|-------------|

**Vital Signs Details**

|     |                       |          |
|-----|-----------------------|----------|
| 2.a | Record Identifier:    | 1        |
|     | Temperature:          | [36.4]   |
|     | Unit:                 | C        |
|     | Temperature Location: | FOREHEAD |

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1217

**Subject No:** 12171044

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

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

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[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/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 | [BPZ9CM] |
|-----|-----------|----------|

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** VACCINATION

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[Form Comments](#)

[eCRF Audit Trail History](#)

**Vaccination**

|     |   |                          |                          |
|-----|---|--------------------------|--------------------------|
| 1.  | Was there a temporary delay of vaccination?   | Not Done<br>_____        | <a href="#">Comments</a> |
| 2.  | Treatment Name  | Not Done<br>_____<br>[ ] | <a href="#">Comments</a> |
| 3.  | Formulation:  | Not Done<br>_____        | <a href="#">Comments</a> |
| 4.  | Dose Date Time:   | Not Done<br>_____<br>//  | <a href="#">Comments</a> |
| 5.  | Anatomical Location:  | Not Done<br>_____        | <a href="#">Comments</a> |
| 6.  | Body Side:  | Not Done<br>_____        | <a href="#">Comments</a> |
| 7.  | Route:  | Not Done<br>_____        | <a href="#">Comments</a> |
| 8.  | Actual Dose:  | Not Done<br>_____<br>[ ] | <a href="#">Comments</a> |
| 9.  | Unit:   | Not Done<br>_____        | <a href="#">Comments</a> |
| 10. | Timeframe Subject Was Observed  | Not Done<br>_____        | <a href="#">Comments</a> |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | Not Done<br>_____        | <a href="#">Comments</a> |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** DATE OF VISIT

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Date of Visit**

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

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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

**Vaccination Symptoms Diary - Symptom Resolved Dates**

|     |   |                               |                          |
|-----|---|-------------------------------|--------------------------|
| 1.  | Were medications to treat fever/pain given on the last day the Subject Diary was completed? | Not Done<br>_____             | <a href="#">Comments</a> |
| 2.a | Symptom:  | FEVER                         |                          |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | Not Done<br>_____             | <a href="#">Comments</a> |
| 2.b | Symptom:  | FATIGUE                       |                          |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | Not Done<br>_____             | <a href="#">Comments</a> |
| 2.c | Symptom:  | HEADACHE                      |                          |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | Not Done<br>_____             | <a href="#">Comments</a> |
| 2.d | Symptom:  | CHILLS                        |                          |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | Not Done<br>_____             | <a href="#">Comments</a> |
| 2.e | Symptom:  | VOMITING                      |                          |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | Not Done<br>_____             | <a href="#">Comments</a> |
| 2.f | Symptom:  | DIARRHEA                      |                          |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | Not Done<br>_____             | <a href="#">Comments</a> |
| 2.g | Symptom:  | NEW OR WORSENERED MUSCLE PAIN |                          |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed?    | Not Done<br>_____             | <a href="#">Comments</a> |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

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

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

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

|     |  |                             |                          |
|-----|--|-----------------------------|--------------------------|
| 2.h | Symptom:   | NEW OR WORSENERD JOINT PAIN |                          |
|     | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | Not Done<br>_____           | <a href="#">Comments</a> |
| 3.  | Injection Site Location:   | Not Done<br>_____           | <a href="#">Comments</a> |
| 4.  | Injection Site Body Side:  | Not Done<br>_____           | <a href="#">Comments</a> |
| 5.a | Injection Site Reaction:   | REDNESS                     |                          |
|     | Were injection site reactions present on the last day the Subject Diary was completed?   | Not Done<br>_____           | <a href="#">Comments</a> |
| 5.b | Injection Site Reaction:   | SWELLING                    |                          |
|     | Were injection site reactions present on the last day the Subject Diary was completed?   | Not Done<br>_____           | <a href="#">Comments</a> |
| 5.c | Injection Site Reaction:   | PAIN AT INJECTION SITE      |                          |
|     | Were injection site reactions present on the last day the Subject Diary was completed?   | Not Done<br>_____           | <a href="#">Comments</a> |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[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/8/2021 |
| 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 | [BN896M] |
| 5.b | Sample ID | [BN896N] |
| 5.c | Sample ID | [BS2S8S] |
| 5.d | Sample ID | [BS2S8T] |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)



**Header Text:** C4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**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:** 1217

**Subject No:** 12171044

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**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:** V5\_MONTH12\_L

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**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:** 1217

**Subject No:** 12171044

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**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:** 1217

**Subject No:** 12171044

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**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:** 1217

**Subject No:** 12171044

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**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 on Nov/12/2020      **Form:** DATE OF VISIT - ILLNESS ONSET

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Nov/12/2020 |
| 2. | Erroneous Visit |             |

**COVID-19 Illness Visit**

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

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Not Complete

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Signs and Symptoms**

|    |                                |  |                          |
|----|--------------------------------|--|--------------------------|
| 1. | Date of Assessment:            | Nov/12/2020  |                          |
| 2. | Date of First Symptom Started: | Nov/10/2020  |                          |
| 3. | Symptoms Ongoing?              | NO<br>Date of Last Symptom Resolved:<br>Feb/9/2021 | <a href="#">Comments</a> |

**Symptoms**

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

**Symptoms - Other**

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

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**Header Text:** C4591001

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

**Form:** MICROBIOLOGY SPECIMEN

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

| #  | Date of Collection | Specimen Type    | Specimen Collection Location | Assay Code and Description                      | Device Type                | Form Instance                   |
|----|--------------------|------------------|------------------------------|---|----------------------------|---------------------------------|
| 1. | Nov/10/2020        | SWABBED MATERIAL | NASOPHARYNX                  | SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 | SARS-COV-2 DIAGNOSTIC TEST | <a href="#">Repeating Pages</a> |
| 2. | Nov/16/2020        | SWABBED MATERIAL | NASOPHARYNX                  | SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 | SARS-COV-2 DIAGNOSTIC TEST | <a href="#">Repeating Pages</a> |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** MICROBIOLOGY SPECIMEN

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Microbiology Specimen**

|    |                               |  |                          |
|----|-------------------------------|--|--------------------------|
| 1. | Actual Date of Collection:    | Nov/10/2020                              |                          |
| 2. | Specimen Type:                | SWABBED MATERIAL                         |                          |
| 3. | Specimen Collection Location: | NASOPHARYNX                              |                          |
| 4. | Assay Code and Description:   | SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2 |                          |
| 5. | Device Type:                  | SARS-COV-2 DIAGNOSTIC TEST               |                          |
| 6. | Trade Name:                   | OTHER                                    |                          |
| 7. | Test Result:                  | POSITIVE                                 |                          |
| 8. | Comments/Findings/Details:    | [ ]                                      |                          |
| 9. | Trade Name Other, Specify:    | [CORONEX-COVID 19 RT-qPCR Test]          | <a href="#">Comments</a> |

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** MICROBIOLOGY SPECIMEN

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Microbiology Specimen**

|    |                               |  |                          |
|----|-------------------------------|--|--------------------------|
| 1. | Actual Date of Collection:    | Nov/16/2020                              |                          |
| 2. | Specimen Type:                | SWABBED MATERIAL                         |                          |
| 3. | Specimen Collection Location: | NASOPHARYNX                              |                          |
| 4. | Assay Code and Description:   | SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2 |                          |
| 5. | Device Type:                  | SARS-COV-2 DIAGNOSTIC TEST               |                          |
| 6. | Trade Name:                   | OTHER                                    |                          |
| 7. | Test Result:                  | POSITIVE                                 |                          |
| 8. | Comments/Findings/Details:    | [ ]                                      |                          |
| 9. | Trade Name Other, Specify:    | [NALT Unknown]                           | <a href="#">Comments</a> |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020      **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Electronic Sample Tracking**

|    |  |  |                          |
|----|--|--|--------------------------|
| 1. | Data Origin  | SITE   | <a href="#">Comments</a> |
| 2. | Sample Type  | NASAL_SWAB_SELF  | <a href="#">Comments</a> |
| 3. | Sample Collected?  | NO   | <a href="#">Comments</a> |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [the nasal swab was collected in the hospital.patient has not used SELF SWAB kit.] | <a href="#">Comments</a> |

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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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>Nov/12/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ]                                       |

**Aliquot**

Please enter barcode for each aliquot.

|     |           |          |
|-----|-----------|----------|
| 5.a | Sample ID | [BPZ9GC] |
|-----|-----------|----------|

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** HEALTH CARE UTILIZATION**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1217**Site Name:** (1217) Kocaeli University Faculty of Medicine**Subject No:** 12171044**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[eCRF Audit Trail History](#)**Health Care Utilization**

|     |                                       |   |
|-----|---------------------------------------|---|
| 1.a | Physician or Healthcare Professional: | SPECIALIST                                  |
|     | Occurrence of Visits or Contacts:     | YES<br>Number of Visits or Contacts:<br>[2] |
| 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? | YES<br>Has the subject been in intensive care due to potential COVID-19 illness?<br>NO |
|----|--|--|

**Header Text:** C4591001

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

**Form:** HOSPITALIZATION DETAILS

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

| #  | Hospitalization Category | Hospitalization Term | Admission Date | Ongoing                              | Form Instance                   |
|----|--------------------------|----------------------|----------------|--------------------------------------|---------------------------------|
| 1. | HOSPITALIZATION STATUS   | HOSPITAL             | Nov/11/2020    | NO<br>Discharge Date:<br>Nov/16/2020 | <a href="#">Repeating Pages</a> |
| 2. | HOSPITALIZATION STATUS   | HOSPITAL             | Nov/20/2020    | NO<br>Discharge Date:<br>Nov/29/2020 | <a href="#">Repeating Pages</a> |

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** HOSPITALIZATION DETAILS

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Hospitalization Details**

|    |                           |                                      |
|----|---------------------------|--------------------------------------|
| 1. | Hospitalization Category: | HOSPITALIZATION STATUS               |
| 2. | Hospitalization Term:     | HOSPITAL                             |
| 3. | Admission Date:           | Nov/11/2020                          |
| 4. | Ongoing?                  | NO<br>Discharge Date:<br>Nov/16/2020 |



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** HOSPITALIZATION DETAILS

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Hospitalization Details**

|    |                           |                                      |
|----|---------------------------|--------------------------------------|
| 1. | Hospitalization Category: | HOSPITALIZATION STATUS               |
| 2. | Hospitalization Term:     | HOSPITAL                             |
| 3. | Admission Date:           | Nov/20/2020                          |
| 4. | Ongoing?                  | NO<br>Discharge Date:<br>Nov/29/2020 |

Header Text: C4591001

Visit: POT\_COVID\_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

| #          | Treatment Identifier | Con Non-Drug Treatments Pre-specified | Treatment                                  | Treatment                                  | Start Date  | Form Instance                   |
|------------|----------------------|---------------------------------------|--|--|-------------|---------------------------------|
| 1.         | 1                    | YES                                   | NON-INVASIVE POSITIVE PRESSURE VENTILATION | NON-INVASIVE POSITIVE PRESSURE VENTILATION | Nov/20/2020 | <a href="#">Repeating Pages</a> |
| 2. DELETED | 2                    | YES                                   | HIGH FLOW OXYGEN THERAPY                   | HIGH FLOW OXYGEN THERAPY                   | Nov/20/2020 | <a href="#">Repeating Pages</a> |
| 3.         | 3                    | YES                                   | HIGH FLOW OXYGEN THERAPY                   | HIGH FLOW OXYGEN THERAPY                   | Nov/22/2020 | <a href="#">Repeating Pages</a> |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** RESPIRATORY TREATMENT

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Respiratory Treatment**

|    |   |  |                          |
|----|---|--|--------------------------|
| 1. | What is the treatment Identifier?             | [1]  |                          |
| 2. | Concomitant Non-drug Treatment Pre-specified: | YES  |                          |
| 3. | Treatment:                                    | NON-INVASIVE POSITIVE PRESSURE VENTILATION   | <a href="#">Comments</a> |
| 4. | Treatment:                                    | [NON-INVASIVE POSITIVE PRESSURE VENTILATION] |                          |
| 5. | Start Date:                                   | Nov/20/2020                                  | <a href="#">Comments</a> |
| 6. | Ongoing?                                      | NO<br>End Date:<br>Nov/21/2020               | <a href="#">Comments</a> |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT  
Nov/12/2020

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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

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**Respiratory Treatment**

|    |   |                                |
|----|---|--------------------------------|
| 1. | What is the treatment Identifier?             | [2]                            |
| 2. | Concomitant Non-drug Treatment Pre-specified: | YES                            |
| 3. | Treatment:                                    | HIGH FLOW OXYGEN THERAPY       |
| 4. | Treatment:                                    | [HIGH FLOW OXYGEN THERAPY]     |
| 5. | Start Date:                                   | Nov/20/2020                    |
| 6. | Ongoing?                                      | NO<br>End Date:<br>Nov/21/2020 |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** RESPIRATORY TREATMENT

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Respiratory Treatment**

|    |   |                                |
|----|---|--------------------------------|
| 1. | What is the treatment Identifier?             | [3]                            |
| 2. | Concomitant Non-drug Treatment Pre-specified: | YES                            |
| 3. | Treatment:                                    | HIGH FLOW OXYGEN THERAPY       |
| 4. | Treatment:                                    | [HIGH FLOW OXYGEN THERAPY]     |
| 5. | Start Date:                                   | Nov/22/2020                    |
| 6. | Ongoing?                                      | NO<br>End Date:<br>Nov/28/2020 |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** ILLNESS DETAILS

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Illness Details**

|    |  |  |                          |
|----|--|--|--------------------------|
| 1. | Category of Clinical Event:                              | POTENTIAL COVID-19 ILLNESS   | <a href="#">Comments</a> |
| 2. | Was a diagnosis obtained for Potential COVID-19 Illness? | YES<br>Respiratory Illness Diagnosis:<br>[Covid-19]<br><br>Date of Diagnosis:<br>Nov/10/2020 | <a href="#">Comments</a> |
| 3. | Toxicity Grade:  | 2  | <a href="#">Comments</a> |

**Header Text:** C4591001

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

**Form:** ILLNESS DETAILS - SEVERE

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** ILLNESS DETAILS - SEVERE

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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

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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> |



Header Text: C4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 10-Oct-2020 15:58

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

| #  | Category for Lab Test | Vendor Name   | Collection Date: | Specimen Type | Lab Result  | Form Instance                   |         |         |     |                          |      |    |                               |       |    |                                 |      |    |                           |    |    |                |      |                                 |                          |     |    |                 |      |                                 |
|----|-----------------------|---|------------------|---------------|---|---------------------------------|---------|---------|-----|--------------------------|------|----|-------------------------------|-------|----|---------------------------------|------|----|---------------------------|----|----|----------------|------|---------------------------------|--------------------------|-----|----|-----------------|------|---------------------------------|
| 1. | CLINICAL CHEMISTRY    | Kocaeli Universitesi Arastirma ve Uygulama Hastanesi Merkez Laboratuvari, Umuttepe 41380 Kocaeli ,TURKEY                    | Nov/10/2020      | BLOOD         | <table border="1"> <thead> <tr> <th>Sponsor-Defined Identifier</th> <th>Test:</th> <th>Result:</th> </tr> </thead> <tbody> <tr> <td>329</td> <td>C Reactive Protein_PX329</td> <td>6.56</td> </tr> <tr> <td>30</td> <td>Alanine Aminotransferase_PX30</td> <td>43.2</td> </tr> <tr> <td>28</td> <td>Aspartate Aminotransferase_PX28</td> <td>28.9</td> </tr> <tr> <td>35</td> <td>Alkaline Phosphatase_PX35</td> <td>74</td> </tr> <tr> <td>21</td> <td>Bilirubin_PX21</td> <td>0.47</td> </tr> <tr> <td>47</td> <td>Blood Urea Nitrogen_PX47</td> <td>[ ]</td> </tr> <tr> <td>48</td> <td>Creatinine_PX48</td> <td>0.86</td> </tr> </tbody> </table> | Sponsor-Defined Identifier      | Test:   | Result: | 329 | C Reactive Protein_PX329 | 6.56 | 30 | Alanine Aminotransferase_PX30 | 43.2  | 28 | Aspartate Aminotransferase_PX28 | 28.9 | 35 | Alkaline Phosphatase_PX35 | 74 | 21 | Bilirubin_PX21 | 0.47 | 47                              | Blood Urea Nitrogen_PX47 | [ ] | 48 | Creatinine_PX48 | 0.86 | <a href="#">Repeating Pages</a> |
|    |                       |   |                  |               | Sponsor-Defined Identifier  | Test:                           | Result: |         |     |                          |      |    |                               |       |    |                                 |      |    |                           |    |    |                |      |                                 |                          |     |    |                 |      |                                 |
|    |                       |   |                  |               | 329   | C Reactive Protein_PX329        | 6.56    |         |     |                          |      |    |                               |       |    |                                 |      |    |                           |    |    |                |      |                                 |                          |     |    |                 |      |                                 |
|    |                       |   |                  |               | 30  | Alanine Aminotransferase_PX30   | 43.2    |         |     |                          |      |    |                               |       |    |                                 |      |    |                           |    |    |                |      |                                 |                          |     |    |                 |      |                                 |
|    |                       |   |                  |               | 28  | Aspartate Aminotransferase_PX28 | 28.9    |         |     |                          |      |    |                               |       |    |                                 |      |    |                           |    |    |                |      |                                 |                          |     |    |                 |      |                                 |
|    |                       |   |                  |               | 35  | Alkaline Phosphatase_PX35       | 74      |         |     |                          |      |    |                               |       |    |                                 |      |    |                           |    |    |                |      |                                 |                          |     |    |                 |      |                                 |
|    |                       |   |                  |               | 21  | Bilirubin_PX21                  | 0.47    |         |     |                          |      |    |                               |       |    |                                 |      |    |                           |    |    |                |      |                                 |                          |     |    |                 |      |                                 |
|    |                       |   |                  |               | 47  | Blood Urea Nitrogen_PX47        | [ ]     |         |     |                          |      |    |                               |       |    |                                 |      |    |                           |    |    |                |      |                                 |                          |     |    |                 |      |                                 |
| 48 | Creatinine_PX48       | 0.86  |                  |               |   |                                 |         |         |     |                          |      |    |                               |       |    |                                 |      |    |                           |    |    |                |      |                                 |                          |     |    |                 |      |                                 |
| 2. | CLINICAL CHEMISTRY    | Lab Name:Kocaeli Universitesi Arastirma ve Uygulama Hastanesi Merkez Laboratuvari, Address : Umuttepe 41380 Kocaeli ,TURKEY | Nov/16/2020      | BLOOD         | <table border="1"> <thead> <tr> <th>Sponsor-Defined Identifier</th> <th>Test:</th> <th>Result:</th> </tr> </thead> <tbody> <tr> <td>329</td> <td>C Reactive Protein_PX329</td> <td>4.60</td> </tr> <tr> <td>30</td> <td>Alanine Aminotransferase_PX30</td> <td>101.5</td> </tr> <tr> <td>28</td> <td>Aspartate Aminotransferase_PX28</td> <td>49.0</td> </tr> <tr> <td>35</td> <td>Alkaline Phosphatase_PX35</td> <td>50</td> </tr> <tr> <td>21</td> <td>Bilirubin_PX21</td> <td>0.54</td> </tr> </tbody> </table>  | Sponsor-Defined Identifier      | Test:   | Result: | 329 | C Reactive Protein_PX329 | 4.60 | 30 | Alanine Aminotransferase_PX30 | 101.5 | 28 | Aspartate Aminotransferase_PX28 | 49.0 | 35 | Alkaline Phosphatase_PX35 | 50 | 21 | Bilirubin_PX21 | 0.54 | <a href="#">Repeating Pages</a> |                          |     |    |                 |      |                                 |
|    |                       |   |                  |               | Sponsor-Defined Identifier  | Test:                           | Result: |         |     |                          |      |    |                               |       |    |                                 |      |    |                           |    |    |                |      |                                 |                          |     |    |                 |      |                                 |
|    |                       |   |                  |               | 329   | C Reactive Protein_PX329        | 4.60    |         |     |                          |      |    |                               |       |    |                                 |      |    |                           |    |    |                |      |                                 |                          |     |    |                 |      |                                 |
|    |                       |   |                  |               | 30  | Alanine Aminotransferase_PX30   | 101.5   |         |     |                          |      |    |                               |       |    |                                 |      |    |                           |    |    |                |      |                                 |                          |     |    |                 |      |                                 |
|    |                       |   |                  |               | 28  | Aspartate Aminotransferase_PX28 | 49.0    |         |     |                          |      |    |                               |       |    |                                 |      |    |                           |    |    |                |      |                                 |                          |     |    |                 |      |                                 |
|    |                       |   |                  |               | 35  | Alkaline Phosphatase_PX35       | 50      |         |     |                          |      |    |                               |       |    |                                 |      |    |                           |    |    |                |      |                                 |                          |     |    |                 |      |                                 |
|    |                       |   |                  |               | 21  | Bilirubin_PX21                  | 0.54    |         |     |                          |      |    |                               |       |    |                                 |      |    |                           |    |    |                |      |                                 |                          |     |    |                 |      |                                 |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 10-Oct-2020 15:58

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

| #                          | Category for Lab Test           | Vendor Name   | Collection Date: | Specimen Type | Lab Result   | Form Instance              |       |         |     |                          |       |    |                               |       |                                 |                                 |      |    |                           |    |    |                |      |    |                          |    |    |                 |      |                                 |
|----------------------------|---------------------------------|---|------------------|---------------|--|----------------------------|-------|---------|-----|--------------------------|-------|----|-------------------------------|-------|---------------------------------|---------------------------------|------|----|---------------------------|----|----|----------------|------|----|--------------------------|----|----|-----------------|------|---------------------------------|
|                            |                                 |   |                  |               | <table border="1"> <thead> <tr> <th>Sponsor-Defined Identifier</th> <th>Test:</th> <th>Result:</th> </tr> </thead> <tbody> <tr> <td>47</td> <td>Blood Urea Nitrogen_PX47</td> <td>13</td> </tr> <tr> <td>48</td> <td>Creatinine_PX48</td> <td>0.76</td> </tr> </tbody> </table>  | Sponsor-Defined Identifier | Test: | Result: | 47  | Blood Urea Nitrogen_PX47 | 13    | 48 | Creatinine_PX48               | 0.76  |                                 |                                 |      |    |                           |    |    |                |      |    |                          |    |    |                 |      |                                 |
| Sponsor-Defined Identifier | Test:                           | Result:   |                  |               |  |                            |       |         |     |                          |       |    |                               |       |                                 |                                 |      |    |                           |    |    |                |      |    |                          |    |    |                 |      |                                 |
| 47                         | Blood Urea Nitrogen_PX47        | 13  |                  |               |  |                            |       |         |     |                          |       |    |                               |       |                                 |                                 |      |    |                           |    |    |                |      |    |                          |    |    |                 |      |                                 |
| 48                         | Creatinine_PX48                 | 0.76  |                  |               |  |                            |       |         |     |                          |       |    |                               |       |                                 |                                 |      |    |                           |    |    |                |      |    |                          |    |    |                 |      |                                 |
| 3.                         | CLINICAL CHEMISTRY              | Lab Name:Kocaeli Universitesi Arastirma ve Uygulama Hastanesi Merkez Laboratuvari, Address : Umuttepe 41380 Kocaeli ,TURKEY | Nov/20/2020      | BLOOD         | <table border="1"> <thead> <tr> <th>Sponsor-Defined Identifier</th> <th>Test:</th> <th>Result:</th> </tr> </thead> <tbody> <tr> <td>329</td> <td>C Reactive Protein_PX329</td> <td>44.77</td> </tr> <tr> <td>30</td> <td>Alanine Aminotransferase_PX30</td> <td>160.8</td> </tr> <tr> <td>28</td> <td>Aspartate Aminotransferase_PX28</td> <td>66.7</td> </tr> <tr> <td>35</td> <td>Alkaline Phosphatase_PX35</td> <td>53</td> </tr> <tr> <td>21</td> <td>Bilirubin_PX21</td> <td>0.59</td> </tr> <tr> <td>47</td> <td>Blood Urea Nitrogen_PX47</td> <td>13</td> </tr> <tr> <td>48</td> <td>Creatinine_PX48</td> <td>0.93</td> </tr> </tbody> </table> | Sponsor-Defined Identifier | Test: | Result: | 329 | C Reactive Protein_PX329 | 44.77 | 30 | Alanine Aminotransferase_PX30 | 160.8 | 28                              | Aspartate Aminotransferase_PX28 | 66.7 | 35 | Alkaline Phosphatase_PX35 | 53 | 21 | Bilirubin_PX21 | 0.59 | 47 | Blood Urea Nitrogen_PX47 | 13 | 48 | Creatinine_PX48 | 0.93 | <a href="#">Repeating Pages</a> |
| Sponsor-Defined Identifier | Test:                           | Result:   |                  |               |  |                            |       |         |     |                          |       |    |                               |       |                                 |                                 |      |    |                           |    |    |                |      |    |                          |    |    |                 |      |                                 |
| 329                        | C Reactive Protein_PX329        | 44.77   |                  |               |  |                            |       |         |     |                          |       |    |                               |       |                                 |                                 |      |    |                           |    |    |                |      |    |                          |    |    |                 |      |                                 |
| 30                         | Alanine Aminotransferase_PX30   | 160.8   |                  |               |  |                            |       |         |     |                          |       |    |                               |       |                                 |                                 |      |    |                           |    |    |                |      |    |                          |    |    |                 |      |                                 |
| 28                         | Aspartate Aminotransferase_PX28 | 66.7  |                  |               |  |                            |       |         |     |                          |       |    |                               |       |                                 |                                 |      |    |                           |    |    |                |      |    |                          |    |    |                 |      |                                 |
| 35                         | Alkaline Phosphatase_PX35       | 53  |                  |               |  |                            |       |         |     |                          |       |    |                               |       |                                 |                                 |      |    |                           |    |    |                |      |    |                          |    |    |                 |      |                                 |
| 21                         | Bilirubin_PX21                  | 0.59  |                  |               |  |                            |       |         |     |                          |       |    |                               |       |                                 |                                 |      |    |                           |    |    |                |      |    |                          |    |    |                 |      |                                 |
| 47                         | Blood Urea Nitrogen_PX47        | 13  |                  |               |  |                            |       |         |     |                          |       |    |                               |       |                                 |                                 |      |    |                           |    |    |                |      |    |                          |    |    |                 |      |                                 |
| 48                         | Creatinine_PX48                 | 0.93  |                  |               |  |                            |       |         |     |                          |       |    |                               |       |                                 |                                 |      |    |                           |    |    |                |      |    |                          |    |    |                 |      |                                 |
| 4.                         | CLINICAL CHEMISTRY              | Lab Name:Kocaeli Universitesi Arastirma ve Uygulama Hastanesi Merkez Laboratuvari, Address : Umuttepe 41380 Kocaeli ,TURKEY | Nov/23/2020      | BLOOD         | <table border="1"> <thead> <tr> <th>Sponsor-Defined Identifier</th> <th>Test:</th> <th>Result:</th> </tr> </thead> <tbody> <tr> <td>329</td> <td>C Reactive Protein_PX329</td> <td>9.62</td> </tr> <tr> <td>30</td> <td>Alanine Aminotransferase_PX30</td> <td>219.3</td> </tr> </tbody> </table>  | Sponsor-Defined Identifier | Test: | Result: | 329 | C Reactive Protein_PX329 | 9.62  | 30 | Alanine Aminotransferase_PX30 | 219.3 | <a href="#">Repeating Pages</a> |                                 |      |    |                           |    |    |                |      |    |                          |    |    |                 |      |                                 |
| Sponsor-Defined Identifier | Test:                           | Result:   |                  |               |  |                            |       |         |     |                          |       |    |                               |       |                                 |                                 |      |    |                           |    |    |                |      |    |                          |    |    |                 |      |                                 |
| 329                        | C Reactive Protein_PX329        | 9.62  |                  |               |  |                            |       |         |     |                          |       |    |                               |       |                                 |                                 |      |    |                           |    |    |                |      |    |                          |    |    |                 |      |                                 |
| 30                         | Alanine Aminotransferase_PX30   | 219.3   |                  |               |  |                            |       |         |     |                          |       |    |                               |       |                                 |                                 |      |    |                           |    |    |                |      |    |                          |    |    |                 |      |                                 |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 10-Oct-2020 15:58

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

| #  | Category for Lab Test | Vendor Name  | Collection Date: | Specimen Type | Lab Result                 |                                 |         | Form Instance                   |
|----|-----------------------|--|------------------|---------------|----------------------------|---------------------------------|---------|---------------------------------|
|    |                       |  |                  |               | Sponsor-Defined Identifier | Test:                           | Result: |                                 |
|    |                       |  |                  |               | 28                         | Aspartate Aminotransferase_PX28 | 76.4    |                                 |
|    |                       |  |                  |               | 35                         | Alkaline Phosphatase_PX35       | 55      |                                 |
|    |                       |  |                  |               | 21                         | Bilirubin_PX21                  | 0.51    |                                 |
|    |                       |  |                  |               | 47                         | Blood Urea Nitrogen_PX47        | 17      |                                 |
|    |                       |  |                  |               | 48                         | Creatinine_PX48                 | 0.81    |                                 |
|    |                       |  |                  |               |                            |                                 |         |                                 |
| 5. | CLINICAL CHEMISTRY    | Kocaeli Universitesi Arastirma ve Uygulama Hastanesi Merkez Laboratuvari, Umuttepe 41380 Kocaeli ,TURKEY | Nov/29/2020      | BLOOD         | 329                        | C Reactive Protein_PX329        | 1.02    | <a href="#">Repeating Pages</a> |
|    |                       |  |                  |               | 30                         | Alanine Aminotransferase_PX30   | 187.1   |                                 |
|    |                       |  |                  |               | 28                         | Aspartate Aminotransferase_PX28 | 36.3    |                                 |
|    |                       |  |                  |               | 35                         | Alkaline Phosphatase_PX35       | 74      |                                 |
|    |                       |  |                  |               | 21                         | Bilirubin_PX21                  | 0.43    |                                 |
|    |                       |  |                  |               | 47                         | Blood Urea Nitrogen_PX47        | 19      |                                 |
|    |                       |  |                  |               | 48                         | Creatinine_PX48                 | 0.87    |                                 |
|    |                       |  |                  |               |                            |                                 |         |                                 |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Lab Chemistry Details**

|    |                             |  |
|----|-----------------------------|--|
| 1. | Lab Panel:                  | CLINICAL CHEMISTRY   |
| 2. | Laboratory Name and Address | [Kocaeli Universitesi Arastirma ve Uygulama Hastanesi Merkez Laboratuvari, Umuttepe 41380 Kocaeli ,TURKEY] |
| 3. | Collection Date:            | Nov/10/2020  |
| 4. | Specimen Type:              | BLOOD  |

**Lab Result**

|     |             |   |                          |
|-----|-------------|---|--------------------------|
| 5.a | Sponsor ID: | [329]                                     | <a href="#">Comments</a> |
|     | Test:       | C Reactive Protein_PX329                  |                          |
|     | Result:     | [6.56]                                    | <a href="#">Comments</a> |
|     | Not Done:   |   | <a href="#">Comments</a> |
|     | LNMT        | Low<br>[0]<br>High<br>[5]<br>Unit<br>mg/L | <a href="#">Comments</a> |
| 5.b | Sponsor ID: | [30]                                      |                          |
|     | Test:       | Alanine Aminotransferase_PX30             |                          |
|     | Result:     | [43.2]                                    |                          |
|     | Not Done:   |   |                          |
|     | LNMT        | Low<br>[0]<br>High<br>[50]<br>Unit<br>U/L |                          |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

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

**Generated Time (GMT):** 29-Mar-2021 13:11

|     |             |  |
|-----|-------------|--|
| 5.c | Sponsor ID: | [28]   |
|     | Test:       | Aspartate Aminotransferase_PX28                |
|     | Result:     | [28.9]   |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[0]<br>High<br>[50]<br>Unit<br>U/L      |
| 5.d | Sponsor ID: | [35]   |
|     | Test:       | Alkaline Phosphatase_PX35                      |
|     | Result:     | [74]   |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[30]<br>High<br>[120]<br>Unit<br>U/L    |
| 5.e | Sponsor ID: | [21]   |
|     | Test:       | Bilirubin_PX21                                 |
|     | Result:     | [0.47]   |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[0.3]<br>High<br>[1.2]<br>Unit<br>mg/dL |

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**Generated Time (GMT):** 29-Mar-2021 13:11

|     |             |  |
|-----|-------------|--|
| 5 f | Sponsor ID: | [47]   |
|     | Test:       | Blood Urea Nitrogen_PX47                         |
|     | Result:     | [ ]  |
|     | Not Done:   | NOT DONE   |
|     | LNMT        | Low<br>[ ]<br>High<br>[ ]<br>Unit                |
| 5.g | Sponsor ID: | [48]   |
|     | Test:       | Creatinine_PX48                                  |
|     | Result:     | [0.86]   |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[0.67]<br>High<br>[1.17]<br>Unit<br>mg/dL |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

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**Lab Chemistry Details**

|    |                             |  |
|----|-----------------------------|--|
| 1. | Lab Panel:                  | CLINICAL CHEMISTRY   |
| 2. | Laboratory Name and Address | [Lab Name:Kocaeli Universitesi Arastirma ve Uygulama Hastanesi Merkez Laboratuvari, Address: Umuttepe 41380 Kocaeli ,TURKEY] |
| 3. | Collection Date:            | Nov/16/2020  |
| 4. | Specimen Type:              | BLOOD  |

**Lab Result**

|     |             |   |
|-----|-------------|---|
| 5.a | Sponsor ID: | [329]                                     |
|     | Test:       | C Reactive Protein_PX329                  |
|     | Result:     | [4.60]                                    |
|     | Not Done:   |   |
|     | LNMT        | Low<br>[0]<br>High<br>[5]<br>Unit<br>mg/L |
| 5.b | Sponsor ID: | [30]                                      |
|     | Test:       | Alanine Aminotransferase_PX30             |
|     | Result:     | [101.5]                                   |
|     | Not Done:   |   |
|     | LNMT        | Low<br>[0]<br>High<br>[50]<br>Unit<br>U/L |

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

|     |             |  |
|-----|-------------|--|
| 5.c | Sponsor ID: | [28]   |
|     | Test:       | Aspartate Aminotransferase_PX28                |
|     | Result:     | [49.0]   |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[0]<br>High<br>[50]<br>Unit<br>U/L      |
| 5.d | Sponsor ID: | [35]   |
|     | Test:       | Alkaline Phosphatase_PX35                      |
|     | Result:     | [50]   |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[30]<br>High<br>[120]<br>Unit<br>U/L    |
| 5.e | Sponsor ID: | [21]   |
|     | Test:       | Bilirubin_PX21                                 |
|     | Result:     | [0.54]   |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[0.3]<br>High<br>[1.2]<br>Unit<br>mg/dL |

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|     |             |  |
|-----|-------------|--|
| 5 f | Sponsor ID: | [47]   |
|     | Test:       | Blood Urea Nitrogen_PX47                         |
|     | Result:     | [13]   |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[7]<br>High<br>[20]<br>Unit<br>mg/dL      |
| 5.g | Sponsor ID: | [48]   |
|     | Test:       | Creatinine_PX48                                  |
|     | Result:     | [0.76]   |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[0.67]<br>High<br>[1.17]<br>Unit<br>mg/dL |

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**Lab Chemistry Details**

|    |                             |  |
|----|-----------------------------|--|
| 1. | Lab Panel:                  | CLINICAL CHEMISTRY   |
| 2. | Laboratory Name and Address | [Lab Name:Kocaeli Universitesi Arastirma ve Uygulama Hastanesi Merkez Laboratuvari, Address: Umuttepe 41380 Kocaeli ,TURKEY] |
| 3. | Collection Date:            | Nov/20/2020  |
| 4. | Specimen Type:              | BLOOD  |

**Lab Result**

|     |             |   |
|-----|-------------|---|
| 5.a | Sponsor ID: | [329]                                     |
|     | Test:       | C Reactive Protein_PX329                  |
|     | Result:     | [44.77]                                   |
|     | Not Done:   |   |
|     | LNMT        | Low<br>[0]<br>High<br>[5]<br>Unit<br>mg/L |
| 5.b | Sponsor ID: | [30]                                      |
|     | Test:       | Alanine Aminotransferase_PX30             |
|     | Result:     | [160.8]                                   |
|     | Not Done:   |   |
|     | LNMT        | Low<br>[0]<br>High<br>[50]<br>Unit<br>U/L |

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|     |             |  |
|-----|-------------|--|
| 5.c | Sponsor ID: | [28]   |
|     | Test:       | Aspartate Aminotransferase_PX28                |
|     | Result:     | [66.7]   |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[0]<br>High<br>[50]<br>Unit<br>U/L      |
| 5.d | Sponsor ID: | [35]   |
|     | Test:       | Alkaline Phosphatase_PX35                      |
|     | Result:     | [53]   |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[30]<br>High<br>[120]<br>Unit<br>U/L    |
| 5.e | Sponsor ID: | [21]   |
|     | Test:       | Bilirubin_PX21                                 |
|     | Result:     | [0.59]   |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[0.3]<br>High<br>[1.2]<br>Unit<br>mg/dL |

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|     |             |  |
|-----|-------------|--|
| 5 f | Sponsor ID: | [47]   |
|     | Test:       | Blood Urea Nitrogen_PX47                         |
|     | Result:     | [13]   |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[7]<br>High<br>[20]<br>Unit<br>mg/dL      |
| 5.g | Sponsor ID: | [48]   |
|     | Test:       | Creatinine_PX48                                  |
|     | Result:     | [0.93]   |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[0.67]<br>High<br>[1.17]<br>Unit<br>mg/dL |

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**Lab Chemistry Details**

|    |                             |  |
|----|-----------------------------|--|
| 1. | Lab Panel:                  | CLINICAL CHEMISTRY   |
| 2. | Laboratory Name and Address | [Lab Name:Kocaeli Universitesi Arastirma ve Uygulama Hastanesi Merkez Laboratuvari, Address: Umuttepe 41380 Kocaeli ,TURKEY] |
| 3. | Collection Date:            | Nov/23/2020  |
| 4. | Specimen Type:              | BLOOD  |

**Lab Result**

|     |             |   |
|-----|-------------|---|
| 5.a | Sponsor ID: | [329]                                     |
|     | Test:       | C Reactive Protein_PX329                  |
|     | Result:     | [9.62]                                    |
|     | Not Done:   |   |
|     | LNMT        | Low<br>[0]<br>High<br>[5]<br>Unit<br>mg/L |
| 5.b | Sponsor ID: | [30]                                      |
|     | Test:       | Alanine Aminotransferase_PX30             |
|     | Result:     | [219.3]                                   |
|     | Not Done:   |   |
|     | LNMT        | Low<br>[0]<br>High<br>[50]<br>Unit<br>U/L |

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|     |             |  |
|-----|-------------|--|
| 5.c | Sponsor ID: | [28]   |
|     | Test:       | Aspartate Aminotransferase_PX28                |
|     | Result:     | [76.4]   |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[0]<br>High<br>[50]<br>Unit<br>U/L      |
| 5.d | Sponsor ID: | [35]   |
|     | Test:       | Alkaline Phosphatase_PX35                      |
|     | Result:     | [55]   |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[30]<br>High<br>[120]<br>Unit<br>U/L    |
| 5.e | Sponsor ID: | [21]   |
|     | Test:       | Bilirubin_PX21                                 |
|     | Result:     | [0.51]   |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[0.3]<br>High<br>[1.2]<br>Unit<br>mg/dL |

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|     |             |  |
|-----|-------------|--|
| 5 f | Sponsor ID: | [47]   |
|     | Test:       | Blood Urea Nitrogen_PX47                         |
|     | Result:     | [17]   |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[7]<br>High<br>[20]<br>Unit<br>mg/dL      |
| 5.g | Sponsor ID: | [48]   |
|     | Test:       | Creatinine_PX48                                  |
|     | Result:     | [0.81]   |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[0.67]<br>High<br>[1.17]<br>Unit<br>mg/dL |

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**Lab Chemistry Details**

|    |                             |  |
|----|-----------------------------|--|
| 1. | Lab Panel:                  | CLINICAL CHEMISTRY   |
| 2. | Laboratory Name and Address | [Kocaeli Universitesi Arastirma ve Uygulama Hastanesi Merkez Laboratuvari, Umuttepe 41380 Kocaeli ,TURKEY] |
| 3. | Collection Date:            | Nov/29/2020  |
| 4. | Specimen Type:              | BLOOD  |

**Lab Result**

|     |             |   |
|-----|-------------|---|
| 5.a | Sponsor ID: | [329]                                     |
|     | Test:       | C Reactive Protein_PX329                  |
|     | Result:     | [1.02]                                    |
|     | Not Done:   |   |
|     | LNMT        | Low<br>[0]<br>High<br>[5]<br>Unit<br>mg/L |
| 5.b | Sponsor ID: | [30]                                      |
|     | Test:       | Alanine Aminotransferase_PX30             |
|     | Result:     | [187.1]                                   |
|     | Not Done:   |   |
|     | LNMT        | Low<br>[0]<br>High<br>[50]<br>Unit<br>U/L |

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|     |             |  |
|-----|-------------|--|
| 5.c | Sponsor ID: | [28]   |
|     | Test:       | Aspartate Aminotransferase_PX28                |
|     | Result:     | [36.3]   |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[0]<br>High<br>[50]<br>Unit<br>U/L      |
| 5.d | Sponsor ID: | [35]   |
|     | Test:       | Alkaline Phosphatase_PX35                      |
|     | Result:     | [74]   |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[30]<br>High<br>[120]<br>Unit<br>U/L    |
| 5.e | Sponsor ID: | [21]   |
|     | Test:       | Bilirubin_PX21                                 |
|     | Result:     | [0.43]   |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[0.3]<br>High<br>[1.2]<br>Unit<br>mg/dL |

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**Subject No:** 12171044

**Subject Initials:** ---

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

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|     |             |  |
|-----|-------------|--|
| 5 f | Sponsor ID: | [47]   |
|     | Test:       | Blood Urea Nitrogen_PX47                         |
|     | Result:     | [19]   |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[7]<br>High<br>[20]<br>Unit<br>mg/dL      |
| 5.g | Sponsor ID: | [48]   |
|     | Test:       | Creatinine_PX48                                  |
|     | Result:     | [0.87]   |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[0.67]<br>High<br>[1.17]<br>Unit<br>mg/dL |

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 10-Oct-2020 16:02

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

| #                          | Category for Lab Test | Vendor Name (DERIVED)   | Collect ion Date: | Speci men T ype | Lab Result  | Form Insta nce             |          |          |   |                |       |   |                |       |   |                  |       |                                 |               |       |   |                |       |     |                   |       |     |                   |       |     |                 |       |     |                 |       |     |                   |       |                                 |
|----------------------------|-----------------------|---|-------------------|-----------------|---|----------------------------|----------|----------|---|----------------|-------|---|----------------|-------|---|------------------|-------|---------------------------------|---------------|-------|---|----------------|-------|-----|-------------------|-------|-----|-------------------|-------|-----|-----------------|-------|-----|-----------------|-------|-----|-------------------|-------|---------------------------------|
| 1.                         | HEMAT OLOGY           | Kocaeli Universitesi Arastirma ve Uygulama Hastanesi Merkez Laboratuvarı, Umutepe 41380 Kocaeli ,TURKEY                   | Nov/10 /2020      | BLOO D          | <table border="1"> <thead> <tr> <th>Sponsor-Defined Identifier</th> <th>Test:</th> <th>Res ult:</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Hemoglobin_PX1</td> <td>15.11</td> </tr> <tr> <td>2</td> <td>Hematocrit_PX2</td> <td>43.32</td> </tr> <tr> <td>3</td> <td>Erythrocytes_PX3</td> <td>5.101</td> </tr> <tr> <td>5</td> <td>Platelets_PX5</td> <td>240.9</td> </tr> <tr> <td>7</td> <td>Leukocytes_PX7</td> <td>8.658</td> </tr> <tr> <td>608</td> <td>Neutrophils_PX608</td> <td>6.836</td> </tr> <tr> <td>609</td> <td>Eosinophils_PX609</td> <td>0.095</td> </tr> <tr> <td>612</td> <td>Monocytes_PX612</td> <td>0.871</td> </tr> <tr> <td>610</td> <td>Basophils_PX610</td> <td>0.027</td> </tr> <tr> <td>611</td> <td>Lymphocytes_PX611</td> <td>0.830</td> </tr> </tbody> </table> | Sponsor-Defined Identifier | Test:    | Res ult: | 1 | Hemoglobin_PX1 | 15.11 | 2 | Hematocrit_PX2 | 43.32 | 3 | Erythrocytes_PX3 | 5.101 | 5                               | Platelets_PX5 | 240.9 | 7 | Leukocytes_PX7 | 8.658 | 608 | Neutrophils_PX608 | 6.836 | 609 | Eosinophils_PX609 | 0.095 | 612 | Monocytes_PX612 | 0.871 | 610 | Basophils_PX610 | 0.027 | 611 | Lymphocytes_PX611 | 0.830 | <a href="#">Repeating Pages</a> |
|                            |                       |   |                   |                 | Sponsor-Defined Identifier  | Test:                      | Res ult: |          |   |                |       |   |                |       |   |                  |       |                                 |               |       |   |                |       |     |                   |       |     |                   |       |     |                 |       |     |                 |       |     |                   |       |                                 |
|                            |                       |   |                   |                 | 1   | Hemoglobin_PX1             | 15.11    |          |   |                |       |   |                |       |   |                  |       |                                 |               |       |   |                |       |     |                   |       |     |                   |       |     |                 |       |     |                 |       |     |                   |       |                                 |
|                            |                       |   |                   |                 | 2   | Hematocrit_PX2             | 43.32    |          |   |                |       |   |                |       |   |                  |       |                                 |               |       |   |                |       |     |                   |       |     |                   |       |     |                 |       |     |                 |       |     |                   |       |                                 |
|                            |                       |   |                   |                 | 3   | Erythrocytes_PX3           | 5.101    |          |   |                |       |   |                |       |   |                  |       |                                 |               |       |   |                |       |     |                   |       |     |                   |       |     |                 |       |     |                 |       |     |                   |       |                                 |
|                            |                       |   |                   |                 | 5   | Platelets_PX5              | 240.9    |          |   |                |       |   |                |       |   |                  |       |                                 |               |       |   |                |       |     |                   |       |     |                   |       |     |                 |       |     |                 |       |     |                   |       |                                 |
|                            |                       |   |                   |                 | 7   | Leukocytes_PX7             | 8.658    |          |   |                |       |   |                |       |   |                  |       |                                 |               |       |   |                |       |     |                   |       |     |                   |       |     |                 |       |     |                 |       |     |                   |       |                                 |
|                            |                       |   |                   |                 | 608   | Neutrophils_PX608          | 6.836    |          |   |                |       |   |                |       |   |                  |       |                                 |               |       |   |                |       |     |                   |       |     |                   |       |     |                 |       |     |                 |       |     |                   |       |                                 |
|                            |                       |   |                   |                 | 609   | Eosinophils_PX609          | 0.095    |          |   |                |       |   |                |       |   |                  |       |                                 |               |       |   |                |       |     |                   |       |     |                   |       |     |                 |       |     |                 |       |     |                   |       |                                 |
|                            |                       |   |                   |                 | 612   | Monocytes_PX612            | 0.871    |          |   |                |       |   |                |       |   |                  |       |                                 |               |       |   |                |       |     |                   |       |     |                   |       |     |                 |       |     |                 |       |     |                   |       |                                 |
|                            |                       |   |                   |                 | 610   | Basophils_PX610            | 0.027    |          |   |                |       |   |                |       |   |                  |       |                                 |               |       |   |                |       |     |                   |       |     |                   |       |     |                 |       |     |                 |       |     |                   |       |                                 |
| 611                        | Lymphocytes_PX611     | 0.830   |                   |                 |   |                            |          |          |   |                |       |   |                |       |   |                  |       |                                 |               |       |   |                |       |     |                   |       |     |                   |       |     |                 |       |     |                 |       |     |                   |       |                                 |
| 2.                         | HEMAT OLOGY           | Lab Name:Kocaeli Universitesi Arastirma ve Uygulama Hastanesi Merkez Laboratuvarı, Address: Umutepe 41380 Kocaeli ,TURKEY | Nov/16 /2020      | BLOO D          | <table border="1"> <thead> <tr> <th>Sponsor-Defined Identifier</th> <th>Test:</th> <th>Res ult:</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Hemoglobin_PX1</td> <td>16.17</td> </tr> <tr> <td>2</td> <td>Hematocrit_PX2</td> <td>45.27</td> </tr> <tr> <td>3</td> <td>Erythrocytes_PX3</td> <td>5.355</td> </tr> </tbody> </table>  | Sponsor-Defined Identifier | Test:    | Res ult: | 1 | Hemoglobin_PX1 | 16.17 | 2 | Hematocrit_PX2 | 45.27 | 3 | Erythrocytes_PX3 | 5.355 | <a href="#">Repeating Pages</a> |               |       |   |                |       |     |                   |       |     |                   |       |     |                 |       |     |                 |       |     |                   |       |                                 |
| Sponsor-Defined Identifier | Test:                 | Res ult:  |                   |                 |   |                            |          |          |   |                |       |   |                |       |   |                  |       |                                 |               |       |   |                |       |     |                   |       |     |                   |       |     |                 |       |     |                 |       |     |                   |       |                                 |
| 1                          | Hemoglobin_PX1        | 16.17   |                   |                 |   |                            |          |          |   |                |       |   |                |       |   |                  |       |                                 |               |       |   |                |       |     |                   |       |     |                   |       |     |                 |       |     |                 |       |     |                   |       |                                 |
| 2                          | Hematocrit_PX2        | 45.27   |                   |                 |   |                            |          |          |   |                |       |   |                |       |   |                  |       |                                 |               |       |   |                |       |     |                   |       |     |                   |       |     |                 |       |     |                 |       |     |                   |       |                                 |
| 3                          | Erythrocytes_PX3      | 5.355   |                   |                 |   |                            |          |          |   |                |       |   |                |       |   |                  |       |                                 |               |       |   |                |       |     |                   |       |     |                   |       |     |                 |       |     |                 |       |     |                   |       |                                 |

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Form Version: 10-Oct-2020 16:02

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Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

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| #  | Category for Lab Test | Vendor Name (DERIVED)  | Collection Date: | Specimen Type | Lab Result                 |                   |         | Form Instance                   |
|----|-----------------------|--|------------------|---------------|----------------------------|-------------------|---------|---------------------------------|
|    |                       |  |                  |               | Sponsor-Defined Identifier | Test:             | Result: |                                 |
|    |                       |  |                  |               |                            |                   |         |                                 |
|    |                       |  |                  |               |                            | 3                 |         |                                 |
|    |                       |  |                  |               | 5                          | Platelets_PX5     | 200.6   |                                 |
|    |                       |  |                  |               | 7                          | Leukocytes_PX7    | 7.15    |                                 |
|    |                       |  |                  |               | 608                        | Neutrophils_PX608 | 5.596   |                                 |
|    |                       |  |                  |               | 609                        | Eosinophils_PX609 | 0.000   |                                 |
|    |                       |  |                  |               | 612                        | Monocytes_PX612   | 0.386   |                                 |
|    |                       |  |                  |               | 610                        | Basophils_PX610   | 0.015   |                                 |
|    |                       |  |                  |               | 611                        | Lymphocytes_PX611 | 1.118   |                                 |
| 3. | HEMATOLOGY            | Lab Name:Kocaeli Universitesi Arastirma ve Uygulama Hastanesi Merkez Laboratuvari, Address: Umuttepe 41380 Kocaeli ,TURKEY | Nov/20/2020      | BLOOD         |                            |                   |         | <a href="#">Repeating Pages</a> |
|    |                       |  |                  |               |                            |                   |         |                                 |
|    |                       |  |                  |               | 1                          | Hemoglobin_PX1    | 14.94   |                                 |
|    |                       |  |                  |               | 2                          | Hematocrit_PX2    | 42.58   |                                 |
|    |                       |  |                  |               | 3                          | Erythrocytes_PX3  | 5.060   |                                 |
|    |                       |  |                  |               | 5                          | Platelets_PX5     | 208.8   |                                 |
|    |                       |  |                  |               | 7                          | Leukocytes_PX7    | 10.915  |                                 |

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| #  | Category for Lab Test | Vendor Name (DERIVED)  | Collection Date: | Specimen Type | Lab Result                 |                   |         | Form Instance                   |
|----|-----------------------|--|------------------|---------------|----------------------------|-------------------|---------|---------------------------------|
|    |                       |  |                  |               | Sponsor-Defined Identifier | Test:             | Result: |                                 |
|    |                       |  |                  |               | 608                        | Neutrophils_PX608 | 8.717   |                                 |
|    |                       |  |                  |               | 609                        | Eosinophils_PX609 | 0.001   |                                 |
|    |                       |  |                  |               | 612                        | Monocytes_PX612   | 0.939   |                                 |
|    |                       |  |                  |               | 610                        | Basophils_PX610   | 0.031   |                                 |
|    |                       |  |                  |               | 611                        | Lymphocytes_PX611 | 1.226   |                                 |
| 4. | HEMATOLOGY            | Lab Name:Kocaeli Universitesi Arastirma ve Uygulama Hastanesi Merkez Laboratuvari, Address: Umuttepe 41380 Kocaeli ,TURKEY | Nov/23/2020      | BLOOD         | 1                          | Hemoglobin_PX1    | 14.81   | <a href="#">Repeating Pages</a> |
|    |                       |  |                  |               | 2                          | Hematocrit_PX2    | 42.79   |                                 |
|    |                       |  |                  |               | 3                          | Erythrocytes_PX3  | 5.152   |                                 |
|    |                       |  |                  |               | 5                          | Platelets_PX5     | 304.7   |                                 |
|    |                       |  |                  |               | 7                          | Leukocytes_PX7    | 7.710   |                                 |
|    |                       |  |                  |               | 608                        | Neutrophils_PX608 | 5.273   |                                 |
|    |                       |  |                  |               | 609                        | Eosinophils_PX609 | 0.053   |                                 |
|    |                       |  |                  |               | 612                        | Monocyt           | 0.4     |                                 |

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| #  | Category for Lab Test | Vendor Name (DERIVED)  | Collection Date: | Specimen Type | Lab Result                 |                   |         | Form Instance                   |
|----|-----------------------|--|------------------|---------------|----------------------------|-------------------|---------|---------------------------------|
|    |                       |  |                  |               | Sponsor-Defined Identifier | Test:             | Result: |                                 |
|    |                       |  |                  |               |                            |                   |         |                                 |
|    |                       |  |                  |               |                            | es_PX612          | 78      |                                 |
|    |                       |  |                  |               | 610                        | Basophils_PX610   | 0.048   |                                 |
|    |                       |  |                  |               | 611                        | Lymphocytes_PX611 | 1.858   |                                 |
| 5. | HEMATOLOGY            | Kocaeli Universitesi Arastirma ve Uygulama Hastanesi Merkez Laboratuvari, Umuttepe 41380 Kocaeli ,TURKEY | Nov/29/2020      | BLOOD         |                            |                   |         | <a href="#">Repeating Pages</a> |
|    |                       |  |                  |               |                            |                   |         |                                 |
|    |                       |  |                  |               | 1                          | Hemoglobin_PX1    | 14.53   |                                 |
|    |                       |  |                  |               | 2                          | Hematocrit_PX2    | 43.33   |                                 |
|    |                       |  |                  |               | 3                          | Erythrocytes_PX3  | 5.111   |                                 |
|    |                       |  |                  |               | 5                          | Platelets_PX5     | 397.6   |                                 |
|    |                       |  |                  |               | 7                          | Leukocytes_PX7    | 18.281  |                                 |
|    |                       |  |                  |               | 608                        | Neutrophils_PX608 | 13.698  |                                 |
|    |                       |  |                  |               | 609                        | Eosinophils_PX609 | 0.086   |                                 |
|    |                       |  |                  |               | 612                        | Monocytes_PX612   | 1.327   |                                 |
|    |                       |  |                  |               | 610                        | Basophils_PX610   | 0.060   |                                 |
|    |                       |  |                  |               | 611                        | Lymphoc           | 3.1     |                                 |

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| # | Category for Lab Test | Vendor Name (DERIVED) | Collection Date: | Specimen Type | Lab Result                 |                |         | Form Instance |
|---|-----------------------|-----------------------|------------------|---------------|----------------------------|----------------|---------|---------------|
|   |                       |                       |                  |               | Sponsor-Defined Identifier | Test:          | Result: |               |
|   |                       |                       |                  |               |                            | ytes_PX<br>611 | 10      |               |

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**Laboratory Data Hematology**

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|----|-----------------------------|--|
| 1. | Lab Panel:                  | HEMATOLOGY   |
| 2. | Laboratory Name and Address | [Kocaeli Universitesi Arastirma ve Uygulama Hastanesi Merkez Laboratuvari, Umuttepe 41380 Kocaeli ,TURKEY] |
| 3. | Collection Date:            | Nov/10/2020  |
| 4. | Specimen Type:              | BLOOD  |

**Lab Result**

|     |             |   |
|-----|-------------|---|
| 5.a | Sponsor ID: | [1]   |
|     | Test:       | Hemoglobin_PX1                                  |
|     | Result:     | [15.11]   |
|     | Not Done:   |   |
|     | LNMT        | Low<br>[12.5]<br>High<br>[16.3]<br>Unit<br>g/dL |
| 5.b | Sponsor ID: | [2]   |
|     | Test:       | Hematocrit_PX2                                  |
|     | Result:     | [43.32]   |
|     | Not Done:   |   |
|     | LNMT        | Low<br>[36.7]<br>High<br>[47.1]<br>Unit<br>%    |

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|     |             |  |
|-----|-------------|--|
| 5.c | Sponsor ID: | [3]  |
|     | Test:       | Erythrocytes_PX3   |
|     | Result:     | [5.101]  |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[4.06]<br>High<br>[5.63]<br>Unit<br>10 <sup>12</sup> /L |
| 5.d | Sponsor ID: | [5]  |
|     | Test:       | Platelets_PX5  |
|     | Result:     | [240.9]  |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[152]<br>High<br>[348]<br>Unit<br>10 <sup>3</sup> /uL   |
| 5.e | Sponsor ID: | [7]  |
|     | Test:       | Leukocytes_PX7   |
|     | Result:     | [8.658]  |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[3.6]<br>High<br>[10.2]<br>Unit<br>10 <sup>3</sup> /uL  |

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|     |             |  |
|-----|-------------|--|
| 5 f | Sponsor ID: | [608]  |
|     | Test:       | Neutrophils_PX608  |
|     | Result:     | [6.836]  |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[1.7]<br>High<br>[7.6]<br>Unit<br>10 <sup>3</sup> /uL |
| 5.g | Sponsor ID: | [609]  |
|     | Test:       | Eosinophils_PX609  |
|     | Result:     | [0.095]  |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[0]<br>High<br>[0.5]<br>Unit<br>10 <sup>3</sup> /uL   |
| 5.h | Sponsor ID: | [612]  |
|     | Test:       | Monocytes_PX612  |
|     | Result:     | [0.871]  |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[0.3]<br>High<br>[1.1]<br>Unit<br>10 <sup>3</sup> /uL |

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|     |             |  |                          |
|-----|-------------|--|--------------------------|
| 5.i | Sponsor ID: | [610]  |                          |
|     | Test:       | Basophils_PX610                                |                          |
|     | Result:     | [0.027]  |                          |
|     | Not Done:   |  |                          |
|     | LNMT        | Low<br>[0]<br>High<br>[0.1]<br>Unit<br>10^3/uL |                          |
| 5.j | Sponsor ID: | [611]  | <a href="#">Comments</a> |
|     | Test:       | Lymphocytes_PX611                              |                          |
|     | Result:     | [0.830]  | <a href="#">Comments</a> |
|     | Not Done:   |  | <a href="#">Comments</a> |
|     | LNMT        | Low<br>[1]<br>High<br>[3.2]<br>Unit<br>10^3/uL | <a href="#">Comments</a> |

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**Laboratory Data Hematology**

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| 1. | Lab Panel:                  | HEMATOLOGY   |
| 2. | Laboratory Name and Address | [Lab Name:Kocaeli Universitesi Arastirma ve Uygulama Hastanesi Merkez Laboratuvari, Address: Umuttepe 41380 Kocaeli ,TURKEY] |
| 3. | Collection Date:            | Nov/16/2020  |
| 4. | Specimen Type:              | BLOOD  |

**Lab Result**

|     |             |   |
|-----|-------------|---|
| 5.a | Sponsor ID: | [1]   |
|     | Test:       | Hemoglobin_PX1                                  |
|     | Result:     | [16.17]   |
|     | Not Done:   |   |
|     | LNMT        | Low<br>[12.5]<br>High<br>[16.3]<br>Unit<br>g/dL |
| 5.b | Sponsor ID: | [2]   |
|     | Test:       | Hematocrit_PX2                                  |
|     | Result:     | [45.27]   |
|     | Not Done:   |   |
|     | LNMT        | Low<br>[36.7]<br>High<br>[47.1]<br>Unit<br>%    |

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|     |             |  |
|-----|-------------|--|
| 5.c | Sponsor ID: | [3]  |
|     | Test:       | Erythrocytes_PX3   |
|     | Result:     | [5.355]  |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[4.06]<br>High<br>[5.63]<br>Unit<br>10 <sup>12</sup> /L |
| 5.d | Sponsor ID: | [5]  |
|     | Test:       | Platelets_PX5  |
|     | Result:     | [200.6]  |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[152]<br>High<br>[348]<br>Unit<br>10 <sup>3</sup> /uL   |
| 5.e | Sponsor ID: | [7]  |
|     | Test:       | Leukocytes_PX7   |
|     | Result:     | [7.115]  |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[3.6]<br>High<br>[10.2]<br>Unit<br>10 <sup>3</sup> /uL  |

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|     |             |  |
|-----|-------------|--|
| 5 f | Sponsor ID: | [608]  |
|     | Test:       | Neutrophils_PX608  |
|     | Result:     | [5.596]  |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[1.7]<br>High<br>[7.6]<br>Unit<br>10 <sup>3</sup> /uL |
| 5.g | Sponsor ID: | [609]  |
|     | Test:       | Eosinophils_PX609  |
|     | Result:     | [0.000]  |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[0]<br>High<br>[0.5]<br>Unit<br>10 <sup>3</sup> /uL   |
| 5.h | Sponsor ID: | [612]  |
|     | Test:       | Monocytes_PX612  |
|     | Result:     | [0.386]  |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[0.3]<br>High<br>[1.1]<br>Unit<br>10 <sup>3</sup> /uL |

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|     |             |  |
|-----|-------------|--|
| 5.i | Sponsor ID: | [610]  |
|     | Test:       | Basophils_PX610                                |
|     | Result:     | [0.015]  |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[0]<br>High<br>[0.1]<br>Unit<br>10^3/uL |
| 5.j | Sponsor ID: | [611]  |
|     | Test:       | Lymphocytes_PX611                              |
|     | Result:     | [1.118]  |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[1]<br>High<br>[3.2]<br>Unit<br>10^3/uL |

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| 1. | Lab Panel:                  | HEMATOLOGY   |
| 2. | Laboratory Name and Address | [Lab Name:Kocaeli Universitesi Arastirma ve Uygulama Hastanesi Merkez Laboratuvari, Address: Umuttepe 41380 Kocaeli ,TURKEY] |
| 3. | Collection Date:            | Nov/20/2020  |
| 4. | Specimen Type:              | BLOOD  |

**Lab Result**

|     |             |   |
|-----|-------------|---|
| 5.a | Sponsor ID: | [1]   |
|     | Test:       | Hemoglobin_PX1                                  |
|     | Result:     | [14.94]   |
|     | Not Done:   |   |
|     | LNMT        | Low<br>[12.5]<br>High<br>[16.3]<br>Unit<br>g/dL |
| 5.b | Sponsor ID: | [2]   |
|     | Test:       | Hematocrit_PX2                                  |
|     | Result:     | [42.58]   |
|     | Not Done:   |   |
|     | LNMT        | Low<br>[36.7]<br>High<br>[47.1]<br>Unit<br>%    |

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|     |             |  |
|-----|-------------|--|
| 5.c | Sponsor ID: | [3]  |
|     | Test:       | Erythrocytes_PX3   |
|     | Result:     | [5.060]  |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[4.06]<br>High<br>[5.63]<br>Unit<br>10 <sup>12</sup> /L |
| 5.d | Sponsor ID: | [5]  |
|     | Test:       | Platelets_PX5  |
|     | Result:     | [208.8]  |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[152]<br>High<br>[348]<br>Unit<br>10 <sup>3</sup> /uL   |
| 5.e | Sponsor ID: | [7]  |
|     | Test:       | Leukocytes_PX7   |
|     | Result:     | [10.915]   |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[3.6]<br>High<br>[10.2]<br>Unit<br>10 <sup>3</sup> /uL  |

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

|     |             |  |
|-----|-------------|--|
| 5 f | Sponsor ID: | [608]  |
|     | Test:       | Neutrophils_PX608  |
|     | Result:     | [8.717]  |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[1.7]<br>High<br>[7.6]<br>Unit<br>10 <sup>3</sup> /uL |
| 5.g | Sponsor ID: | [609]  |
|     | Test:       | Eosinophils_PX609  |
|     | Result:     | [0.001]  |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[0]<br>High<br>[0.5]<br>Unit<br>10 <sup>3</sup> /uL   |
| 5.h | Sponsor ID: | [612]  |
|     | Test:       | Monocytes_PX612  |
|     | Result:     | [0.939]  |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[0.3]<br>High<br>[1.1]<br>Unit<br>10 <sup>3</sup> /uL |

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020      **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

|     |             |  |
|-----|-------------|--|
| 5.i | Sponsor ID: | [610]  |
|     | Test:       | Basophils_PX610                                |
|     | Result:     | [0.031]  |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[0]<br>High<br>[0.1]<br>Unit<br>10^3/uL |
| 5.j | Sponsor ID: | [611]  |
|     | Test:       | Lymphocytes_PX611                              |
|     | Result:     | [1.226]  |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[1]<br>High<br>[3.2]<br>Unit<br>10^3/uL |

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Laboratory Data Hematology**

|    |                             |  |
|----|-----------------------------|--|
| 1. | Lab Panel:                  | HEMATOLOGY   |
| 2. | Laboratory Name and Address | [Lab Name:Kocaeli Universitesi Arastirma ve Uygulama Hastanesi Merkez Laboratuvari, Address: Umuttepe 41380 Kocaeli ,TURKEY] |
| 3. | Collection Date:            | Nov/23/2020  |
| 4. | Specimen Type:              | BLOOD  |

**Lab Result**

|     |             |   |
|-----|-------------|---|
| 5.a | Sponsor ID: | [1]   |
|     | Test:       | Hemoglobin_PX1                                  |
|     | Result:     | [14.81]   |
|     | Not Done:   |   |
|     | LNMT        | Low<br>[12.5]<br>High<br>[16.3]<br>Unit<br>g/dL |
| 5.b | Sponsor ID: | [2]   |
|     | Test:       | Hematocrit_PX2                                  |
|     | Result:     | [42.79]   |
|     | Not Done:   |   |
|     | LNMT        | Low<br>[36.7]<br>High<br>[47.1]<br>Unit<br>%    |

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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

|     |             |  |
|-----|-------------|--|
| 5.c | Sponsor ID: | [3]  |
|     | Test:       | Erythrocytes_PX3   |
|     | Result:     | [5.152]  |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[4.06]<br>High<br>[5.63]<br>Unit<br>10 <sup>12</sup> /L |
| 5.d | Sponsor ID: | [5]  |
|     | Test:       | Platelets_PX5  |
|     | Result:     | [304.7]  |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[152]<br>High<br>[348]<br>Unit<br>10 <sup>3</sup> /uL   |
| 5.e | Sponsor ID: | [7]  |
|     | Test:       | Leukocytes_PX7   |
|     | Result:     | [7.710]  |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[3.6]<br>High<br>[10.2]<br>Unit<br>10 <sup>3</sup> /uL  |

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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

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

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

**Site No:** 1217

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**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

|     |             |  |
|-----|-------------|--|
| 5 f | Sponsor ID: | [608]  |
|     | Test:       | Neutrophils_PX608  |
|     | Result:     | [5.273]  |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[1.7]<br>High<br>[7.6]<br>Unit<br>10 <sup>3</sup> /uL |
| 5.g | Sponsor ID: | [609]  |
|     | Test:       | Eosinophils_PX609  |
|     | Result:     | [0.053]  |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[0]<br>High<br>[0.5]<br>Unit<br>10 <sup>3</sup> /uL   |
| 5.h | Sponsor ID: | [612]  |
|     | Test:       | Monocytes_PX612  |
|     | Result:     | [0.478]  |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[0.3]<br>High<br>[1.1]<br>Unit<br>10 <sup>3</sup> /uL |

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

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**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

|     |             |  |
|-----|-------------|--|
| 5.i | Sponsor ID: | [610]  |
|     | Test:       | Basophils_PX610                                |
|     | Result:     | [0.048]  |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[0]<br>High<br>[0.1]<br>Unit<br>10^3/uL |
| 5.j | Sponsor ID: | [611]  |
|     | Test:       | Lymphocytes_PX611                              |
|     | Result:     | [1.858]  |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[1]<br>High<br>[3.2]<br>Unit<br>10^3/uL |

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**Laboratory Data Hematology**

|    |                             |  |
|----|-----------------------------|--|
| 1. | Lab Panel:                  | HEMATOLOGY   |
| 2. | Laboratory Name and Address | [Kocaeli Universitesi Arastirma ve Uygulama Hastanesi Merkez Laboratuvari, Umuttepe 41380 Kocaeli ,TURKEY] |
| 3. | Collection Date:            | Nov/29/2020  |
| 4. | Specimen Type:              | BLOOD  |

**Lab Result**

|     |             |   |
|-----|-------------|---|
| 5.a | Sponsor ID: | [1]   |
|     | Test:       | Hemoglobin_PX1                                  |
|     | Result:     | [14.53]   |
|     | Not Done:   |   |
|     | LNMT        | Low<br>[12.5]<br>High<br>[16.3]<br>Unit<br>g/dL |
| 5.b | Sponsor ID: | [2]   |
|     | Test:       | Hematocrit_PX2                                  |
|     | Result:     | [43.33]   |
|     | Not Done:   |   |
|     | LNMT        | Low<br>[36.7]<br>High<br>[47.1]<br>Unit<br>%    |

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**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

|     |             |  |
|-----|-------------|--|
| 5.c | Sponsor ID: | [3]  |
|     | Test:       | Erythrocytes_PX3   |
|     | Result:     | [5.111]  |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[4.06]<br>High<br>[5.63]<br>Unit<br>10 <sup>12</sup> /L |
| 5.d | Sponsor ID: | [5]  |
|     | Test:       | Platelets_PX5  |
|     | Result:     | [397.6]  |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[152]<br>High<br>[348]<br>Unit<br>10 <sup>3</sup> /uL   |
| 5.e | Sponsor ID: | [7]  |
|     | Test:       | Leukocytes_PX7   |
|     | Result:     | [18.281]   |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[3.6]<br>High<br>[10.2]<br>Unit<br>10 <sup>3</sup> /uL  |

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**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

|     |             |  |
|-----|-------------|--|
| 5 f | Sponsor ID: | [608]  |
|     | Test:       | Neutrophils_PX608  |
|     | Result:     | [13.698]   |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[1.7]<br>High<br>[7.6]<br>Unit<br>10 <sup>3</sup> /uL |
| 5.g | Sponsor ID: | [609]  |
|     | Test:       | Eosinophils_PX609  |
|     | Result:     | [0.086]  |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[0]<br>High<br>[0.5]<br>Unit<br>10 <sup>3</sup> /uL   |
| 5.h | Sponsor ID: | [612]  |
|     | Test:       | Monocytes_PX612  |
|     | Result:     | [1.327]  |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[0.3]<br>High<br>[1.1]<br>Unit<br>10 <sup>3</sup> /uL |

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**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

|     |             |  |
|-----|-------------|--|
| 5.i | Sponsor ID: | [610]  |
|     | Test:       | Basophils_PX610                                |
|     | Result:     | [0.060]  |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[0]<br>High<br>[0.1]<br>Unit<br>10^3/uL |
| 5.j | Sponsor ID: | [611]  |
|     | Test:       | Lymphocytes_PX611                              |
|     | Result:     | [3.110]  |
|     | Not Done:   |  |
|     | LNMT        | Low<br>[1]<br>High<br>[3.2]<br>Unit<br>10^3/uL |

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**Header Text:** C4591001

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

**Form:** VITAL SIGNS - COVID

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

| #  | Date:       | Vital Signs Details       |                  |                   | Form Instance                   |
|----|-------------|---------------------------|------------------|-------------------|---------------------------------|
| 1. | Nov/12/2020 | <b>Record Identifier:</b> | <b>Systolic:</b> | <b>Diastolic:</b> | <a href="#">Repeating Pages</a> |
|    |             | 1                         | 130              | 80                |                                 |
| 2. | Nov/20/2020 | <b>Record Identifier:</b> | <b>Systolic:</b> | <b>Diastolic:</b> | <a href="#">Repeating Pages</a> |
|    |             | 1                         | 110              | 70                |                                 |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** VITAL SIGNS - COVID

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Vital Signs**

|    |       |             |
|----|-------|-------------|
| 1. | Date: | Nov/12/2020 |
|----|-------|-------------|

**Vital Signs Details**

|     |  |       |
|-----|--|-------|
| 2.a | Record Identifier:                       | 1     |
|     | Systolic:                                | [130] |
|     | Diastolic:                               | [80]  |
|     | Respiratory Rate in respirations/minute: | [20]  |
|     | Heart Rate in beats/minute:              | [95]  |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** VITAL SIGNS - COVID

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

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**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

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

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**Vital Signs**

|    |       |             |
|----|-------|-------------|
| 1. | Date: | Nov/20/2020 |
|----|-------|-------------|

**Vital Signs Details**

|     |  |       |
|-----|--|-------|
| 2.a | Record Identifier:                       | 1     |
|     | Systolic:                                | [110] |
|     | Diastolic:                               | [70]  |
|     | Respiratory Rate in respirations/minute: | [22]  |
|     | Heart Rate in beats/minute:              | [80]  |

**Header Text:** C4591001

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

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

**Form Version:** 10-Oct-2020 16:04

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

| #  | Date:       | Vital Signs Details       |                          | Form Instance                   |
|----|-------------|---------------------------|--------------------------|---------------------------------|
| 1. | Nov/11/2020 | <b>Record Identifier:</b> | <b>Oxygen Saturation</b> | <a href="#">Repeating Pages</a> |
|    |             | 1                         | 97.0                     |                                 |
| 2. | Nov/20/2020 | <b>Record Identifier:</b> | <b>Oxygen Saturation</b> | <a href="#">Repeating Pages</a> |
|    |             | 1                         | 94.0                     |                                 |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Nov/12/2020

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

**Form Version:** 10-Oct-2020 16:04

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Vital Signs**

|    |       |             |
|----|-------|-------------|
| 1. | Date: | Nov/11/2020 |
|----|-------|-------------|

**Vital Signs Details**

|     |                       |        |
|-----|-----------------------|--------|
| 2.a | Record Identifier:    | 1      |
|     | SPO2 Pulse Oximetry % | [97.0] |



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Nov/12/2020

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

**Form Version:** 10-Oct-2020 16:04

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

**Site No:** 1217

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**Vital Signs**

|    |       |             |
|----|-------|-------------|
| 1. | Date: | Nov/20/2020 |
|----|-------|-------------|

**Vital Signs Details**

|     |                       |        |
|-----|-----------------------|--------|
| 2.a | Record Identifier:    | 1      |
|     | SPO2 Pulse Oximetry % | [94.0] |

**Header Text:** C4591001

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

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

| #  | Date Time of Assessment | Arterial Blood Gases PaO2 | FiO2 (Fraction of Inhaled Oxygen) | Form Instance                   |
|----|-------------------------|---------------------------|-----------------------------------|---------------------------------|
| 1. | Nov/20/2020 18:00       | 65                        | 0.69                              | <a href="#">Repeating Pages</a> |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** OXYGENATION PARAMETERS

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Oxygenation Parameters**

|    |                                    |                   |                          |
|----|------------------------------------|-------------------|--------------------------|
| 1. | Date Time of Assessment:           | Nov/20/2020 18:00 | <a href="#">Comments</a> |
| 2. | Arterial Blood Gases PaO2 (mmHg):  | [65]              | <a href="#">Comments</a> |
| 3. | FiO2 (Fraction of Inhaled Oxygen): | [0.69]            | <a href="#">Comments</a> |

Header Text: C4591001

Visit: POT\_COVID\_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

| #           | Sponsor-Defined Identifier | Category for Medication         | Concomitant Medications Pre-specified | Name of Medication                                      | Start Date  | Form Instance                   |
|-------------|----------------------------|---------------------------------|---------------------------------------|---|-------------|---------------------------------|
| 1. DELETED  | 1                          | GENERAL CONCOMITANT MEDICATIONS | NO                                    | Favipiravir(loading dose:2x1600 mg,oral)                | Nov/11/2020 | <a href="#">Repeating Pages</a> |
| 2. DELETED  | 2                          | GENERAL CONCOMITANT MEDICATIONS | NO                                    | Azithromycin(loading dose;1x500 mg,oral)                | Nov/14/2020 | <a href="#">Repeating Pages</a> |
| 3. DELETED  | 3                          | GENERAL CONCOMITANT MEDICATIONS | NO                                    | PRECORT-LIYO (METHYLPREDNISOLONE,1x 40 mg, IV)          | Nov/15/2020 | <a href="#">Repeating Pages</a> |
| 4. DELETED  | 4                          | GENERAL CONCOMITANT MEDICATIONS | NO                                    | LANSAZOL (Lansoprazole, 30 mg, 1x1 oral)                | Nov/11/2020 | <a href="#">Repeating Pages</a> |
| 5. DELETED  | 5                          | GENERAL CONCOMITANT MEDICATIONS | NO                                    | MUSCORIL (THIOLCHICOSIDE Injection, 4 mg/2 mg, IV, 1x1) | Nov/11/2020 | <a href="#">Repeating Pages</a> |
| 6. DELETED  | 6                          | GENERAL CONCOMITANT MEDICATIONS | NO                                    | OKSAPAR (ENOXAPARIN SODIUM, 1x0.6ml,subcutaneous)       | Nov/11/2020 | <a href="#">Repeating Pages</a> |
| 7. DELETED  | 7                          | GENERAL CONCOMITANT MEDICATIONS | NO                                    | OKSAPAR (ENOXAPARIN SODIUM, 1x0.6 ml,subcutaneous)      | Nov/17/2020 | <a href="#">Repeating Pages</a> |
| 8. DELETED  | 8                          | GENERAL CONCOMITANT MEDICATIONS | NO                                    | DEXAMETHASONE (6 mg, 1x1, oral)                         | Nov/17/2020 | <a href="#">Repeating Pages</a> |
| 9. DELETED  | 9                          | GENERAL CONCOMITANT MEDICATIONS | NO                                    | Azithromycin (1x250 mg,oral)                            | Nov/17/2020 | <a href="#">Repeating Pages</a> |
| 10. DELETED | 10                         | GENERAL CONCOMITANT MEDICATIONS | NO                                    | CLEXANE(ENOXAPARIN SODIUM 1x0.8 mg,subcutaneous)        | Nov/20/2020 | <a href="#">Repeating Pages</a> |
| 11. DELETED | 11                         | GENERAL CONCOMITANT MEDICATIONS | NO                                    | Teicoplanin (1x400 mg IV)                               | Nov/20/2020 | <a href="#">Repeating Pages</a> |
| 12. DELETED | 12                         | GENERAL CONCOMITANT MEDICATIONS | NO                                    | Piperacillin - tazobactam (3x4.5 g/day IV)              | Nov/20/2020 | <a href="#">Repeating Pages</a> |
| 13. DELETED | 13                         | GENERAL CONCOMITANT MEDICATIONS | NO                                    | Tocilizumab (1x400 mg IV)                               | Nov/20/2020 | <a href="#">Repeating Pages</a> |

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Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

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| #           | Sponsor-Defined Identifier | Category for Medication         | Concomitant Medications Pre-specified | Name of Medication                       | Start Date  | Form Instance                   |
|-------------|----------------------------|---------------------------------|---------------------------------------|--|-------------|---------------------------------|
| 14. DELETED | 14                         | GENERAL CONCOMITANT MEDICATIONS | NO                                    | Oxygen mask (12 L/MIN)                   | Nov/20/2020 | <a href="#">Repeating Pages</a> |
| 15. DELETED | 15                         | GENERAL CONCOMITANT MEDICATIONS | NO                                    | Favipiravir(2x600 mg,oral)               | Nov/12/2020 | <a href="#">Repeating Pages</a> |
| 16. DELETED | 16                         | GENERAL CONCOMITANT MEDICATIONS | NO                                    | Azithromycin(1x250 mg,oral)              | Nov/15/2020 | <a href="#">Repeating Pages</a> |
| 17. DELETED | 17                         | GENERAL CONCOMITANT MEDICATIONS | NO                                    | Nasal Cannula oxygen (6 L/MIN)           | Nov/22/2020 | <a href="#">Repeating Pages</a> |
| 18. DELETED | 18                         | GENERAL CONCOMITANT MEDICATIONS | NO                                    | Teicoplanin (loading dose,2x400 mg IV)   | Nov/20/2020 | <a href="#">Repeating Pages</a> |
| 19. DELETED | 19                         | GENERAL CONCOMITANT MEDICATIONS | NO                                    | Lansazol (lansoprazole, 30 mg, 1x1 oral) | Nov/20/2020 | <a href="#">Repeating Pages</a> |
| 20. DELETED | 20                         | GENERAL CONCOMITANT MEDICATIONS | NO                                    | Seralin (sertralin, 50 mg, 1x1 oral)     | Nov/20/2020 | <a href="#">Repeating Pages</a> |

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|    |   |  |                          |
|----|---|--|--------------------------|
| 1. | What is the medication identifier?  | [+]  | <a href="#">Comments</a> |
| 2. | Category:   | GENERAL CONCOMITANT MEDICATIONS            | <a href="#">Comments</a> |
| 3. | Concomitant Medications Pre-specified:  | NO   | <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). | [Favipiravir(loading dose:2x1600 mg,oral)] | <a href="#">Comments</a> |
| 5. | Start Date:   | Nov/11/2020                                | <a href="#">Comments</a> |
| 6. | Ongoing?  | NO<br>End Date:<br>Nov/11/2020             | <a href="#">Comments</a> |

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**Concomitant Medications**

|    |   |  |
|----|---|--|
| 1. | What is the medication identifier?  | [2]  |
| 2. | Category:   | GENERAL CONCOMITANT MEDICATIONS            |
| 3. | Concomitant Medications Pre-specified:  | NO   |
| 4. | Medication:<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). | [Azithromycin(loading dose;1x500 mg,oral)] |
| 5. | Start Date:   | Nov/14/2020                                |
| 6. | Ongoing?  | NO<br>End Date:<br>Nov/14/2020             |

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**Concomitant Medications**

|    |   |   |
|----|---|---|
| 1. | What is the medication identifier?  | [3]   |
| 2. | Category:   | GENERAL CONCOMITANT MEDICATIONS                   |
| 3. | Concomitant Medications Pre-specified:  | NO  |
| 4. | Medication:<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). | [PRECORT LIYO (METHYLPREDNISOLONE, 1x 40 mg, IV)] |
| 5. | Start Date:   | Nov/15/2020                                       |
| 6. | Ongoing?  | NO<br>End Date:<br>Nov/16/2020                    |

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**Concomitant Medications**

|    |   |  |
|----|---|--|
| 1. | What is the medication identifier?  | [4]  |
| 2. | Category:   | GENERAL CONCOMITANT MEDICATIONS            |
| 3. | Concomitant Medications Pre-specified:  | NO   |
| 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). | [LANSAZOL (Lansoprazole, 30 mg, 1x1 oral)] |
| 5. | Start Date:   | Nov/11/2020                                |
| 6. | Ongoing?  | NO<br>End Date:<br>Nov/16/2020             |

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|    |   |   |
|----|---|---|
| 1. | What is the medication identifier?  | [§]   |
| 2. | Category:   | GENERAL CONCOMITANT MEDICATIONS                             |
| 3. | Concomitant Medications Pre-specified:  | NO  |
| 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). | [MUSCORIL (THIocolchicoside Injection, 4 mg/2 mg, IV, 1x1)] |
| 5. | Start Date:   | Nov/11/2020   |
| 6. | Ongoing?  | NO<br>End Date:<br>Nov/16/2020                              |

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**Concomitant Medications**

|    |   |   |
|----|---|---|
| 1. | What is the medication identifier?  | [6]   |
| 2. | Category:   | GENERAL CONCOMITANT MEDICATIONS                     |
| 3. | Concomitant Medications Pre-specified:  | NO  |
| 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). | [OKSAPAR (ENOXAPARIN SODIUM, 1x0.6ml,subcutaneous)] |
| 5. | Start Date:   | Nov/11/2020   |
| 6. | Ongoing?  | NO<br>End Date:<br>Nov/19/2020                      |

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**Concomitant Medications**

|    |   |  |
|----|---|--|
| 1. | What is the medication identifier?  | [Z]  |
| 2. | Category:   | GENERAL CONCOMITANT MEDICATIONS                      |
| 3. | Concomitant Medications Pre-specified:  | NO   |
| 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). | [OKSAPAR (ENOXAPARIN SODIUM, 1x0.6 ml,subcutaneous)] |
| 5. | Start Date:   | Nov/17/2020  |
| 6. | Ongoing?  | NO<br>End Date:<br>Nov/19/2020                       |

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**Concomitant Medications**

|    |   |                                   |
|----|---|-----------------------------------|
| 1. | What is the medication identifier?  | [§]                               |
| 2. | Category:   | GENERAL CONCOMITANT MEDICATIONS   |
| 3. | Concomitant Medications Pre-specified:  | NO                                |
| 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). | [DEXAMETHASONE (6 mg, 1x1, oral)] |
| 5. | Start Date:   | Nov/17/2020                       |
| 6. | Ongoing?  | YES                               |

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**Concomitant Medications**

|    |   |                                 |
|----|---|---------------------------------|
| 1. | What is the medication identifier?  | [9]                             |
| 2. | Category:   | GENERAL CONCOMITANT MEDICATIONS |
| 3. | Concomitant Medications Pre-specified:  | NO                              |
| 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). | [Azithromycin (1x250 mg,oral)]  |
| 5. | Start Date:   | Nov/17/2020                     |
| 6. | Ongoing?  | NO<br>End Date:<br>Nov/19/2020  |

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**Concomitant Medications**

|    |   |  |
|----|---|--|
| 1. | What is the medication identifier?  | [40]   |
| 2. | Category:   | GENERAL CONCOMITANT MEDICATIONS                    |
| 3. | Concomitant Medications Pre-specified:  | NO   |
| 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). | [CLEXANE(ENOXAPARIN SODIUM 1x0.8 mg,subcutaneous)] |
| 5. | Start Date:   | Nov/20/2020  |
| 6. | Ongoing?  | YES  |

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**Concomitant Medications**

|    |   |                                 |
|----|---|---------------------------------|
| 1. | What is the medication identifier?  | [44]                            |
| 2. | Category:   | GENERAL CONCOMITANT MEDICATIONS |
| 3. | Concomitant Medications Pre-specified:  | NO                              |
| 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). | [Teicoplanin (1x400 mg IV)]     |
| 5. | Start Date:   | Nov/20/2020                     |
| 6. | Ongoing?  | NO<br>End Date:<br>Nov/29/2020  |



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**Concomitant Medications**

|    |   |  |
|----|---|--|
| 1. | What is the medication identifier?  | [12]   |
| 2. | Category:   | GENERAL CONCOMITANT MEDICATIONS              |
| 3. | Concomitant Medications Pre-specified:  | NO   |
| 4. | Medication:<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). | [Piperacillin – tazobactam (3x4.5 g/day IV)] |
| 5. | Start Date:   | Nov/20/2020                                  |
| 6. | Ongoing?  | NO<br>End Date:<br>Nov/29/2020               |

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**Concomitant Medications**

|    |   |                                 |
|----|---|---------------------------------|
| 1. | What is the medication identifier?  | [13]                            |
| 2. | Category:   | GENERAL CONCOMITANT MEDICATIONS |
| 3. | Concomitant Medications Pre-specified:  | NO                              |
| 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). | [Tocilizumab (1x400 mg IV)]     |
| 5. | Start Date:   | Nov/20/2020                     |
| 6. | Ongoing?  | NO<br>End Date:<br>Nov/22/2020  |

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**Concomitant Medications**

|    |   |                                 |
|----|---|---------------------------------|
| 1. | What is the medication identifier?  | [14]                            |
| 2. | Category:   | GENERAL CONCOMITANT MEDICATIONS |
| 3. | Concomitant Medications Pre-specified:  | NO                              |
| 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). | [Oxygen mask (12 L/MIN)]        |
| 5. | Start Date:   | Nov/20/2020                     |
| 6. | Ongoing?  | NO<br>End Date:<br>Nov/21/2020  |

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**Concomitant Medications**

|    |   |                                 |
|----|---|---------------------------------|
| 1. | What is the medication identifier?  | [15]                            |
| 2. | Category:   | GENERAL CONCOMITANT MEDICATIONS |
| 3. | Concomitant Medications Pre-specified:  | NO                              |
| 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). | [Favipiravir(2x600 mg,oral)]    |
| 5. | Start Date:   | Nov/12/2020                     |
| 6. | Ongoing?  | NO<br>End Date:<br>Nov/15/2020  |

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**Concomitant Medications**

|    |   |                                 |
|----|---|---------------------------------|
| 1. | What is the medication identifier?  | [16]                            |
| 2. | Category:   | GENERAL CONCOMITANT MEDICATIONS |
| 3. | Concomitant Medications Pre-specified:  | NO                              |
| 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). | [Azithromycin(1x250 mg,oral)]   |
| 5. | Start Date:   | Nov/15/2020                     |
| 6. | Ongoing?  | NO<br>End Date:<br>Nov/16/2020  |

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**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS**Form Version:** 06-Jul-2020 21:55**Form Status:** Data Complete, Deleted, Verified**Site No:** 1217**Site Name:** (1217) Kocaeli University Faculty of Medicine**Subject No:** 12171044**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11

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**Concomitant Medications**

|    |   |                                  |
|----|---|----------------------------------|
| 1. | What is the medication identifier?  | [47]                             |
| 2. | Category:   | GENERAL CONCOMITANT MEDICATIONS  |
| 3. | Concomitant Medications Pre-specified:  | NO                               |
| 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). | [Nasal Cannula oxygen (6 L/MIN)] |
| 5. | Start Date:   | Nov/22/2020                      |
| 6. | Ongoing?  | NO<br>End Date:<br>Nov/28/2020   |

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS**Form Version:** 06-Jul-2020 21:55**Form Status:** Data Complete, Deleted, Verified**Site No:** 1217**Site Name:** (1217) Kocaeli University Faculty of Medicine**Subject No:** 12171044**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11**\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\***

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**Concomitant Medications**

|    |   |   |
|----|---|---|
| 1. | What is the medication identifier?  | [18]                                      |
| 2. | Category:   | GENERAL CONCOMITANT MEDICATIONS           |
| 3. | Concomitant Medications Pre-specified:  | NO  |
| 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). | [Teicoplanin (loading dose, 2x400 mg IV)] |
| 5. | Start Date:   | Nov/20/2020                               |
| 6. | Ongoing?  | NO<br>End Date:<br>Nov/20/2020            |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS  
Nov/12/2020

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

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**Subject Initials:** ---

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

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**Concomitant Medications**

|    |   |  |
|----|---|--|
| 1. | What is the medication identifier?  | [19]                                       |
| 2. | Category:   | GENERAL CONCOMITANT MEDICATIONS            |
| 3. | Concomitant Medications Pre-specified:  | NO   |
| 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). | [Lansazol (lansoprazole, 30 mg, 1x1 oral)] |
| 5. | Start Date:   | Nov/20/2020                                |
| 6. | Ongoing?  | YES  |

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS  
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**Form Status:** Data Complete, Deleted, Verified

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**Concomitant Medications**

|    |   |  |
|----|---|--|
| 1. | What is the medication identifier?  | [20]                                   |
| 2. | Category:   | GENERAL CONCOMITANT MEDICATIONS        |
| 3. | Concomitant Medications Pre-specified:  | NO                                     |
| 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). | [Seralin (sertralin, 50 mg, 1x1 oral)] |
| 5. | Start Date:   | Nov/20/2020                            |
| 6. | Ongoing?  | NO<br>End Date:<br>Nov/29/2020         |

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**Header Text:** C4591001

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

**Form:** IMAGING

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

| #  | Date of Assessment | Location of Assessment | Imaging Method | Overall Assessment  | Form Instance                   |
|----|--------------------|------------------------|----------------|---|---------------------------------|
| 1. | Nov/14/2020        | CHEST                  | CT SCAN        | ABNORMAL<br><i>If abnormal, specify findings:</i><br><br>Report result: COVID-19 category 2; prevalent peripheral ground glass density of the bilateral lung. | <a href="#">Repeating Pages</a> |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** IMAGING  
Nov/12/2020

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

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**Imaging**

|    |                         |  |                          |
|----|-------------------------|--|--------------------------|
| 1. | Date of Assessment:     | Nov/14/2020  | <a href="#">Comments</a> |
| 2. | Location of Assessment: | CHEST  | <a href="#">Comments</a> |
| 3. | Type of Imaging Exam:   | CT SCAN  | <a href="#">Comments</a> |
| 4. | Assessment:             | ABNORMAL<br>If abnormal, specify findings:<br>[Report result: COVID-19 category 2; prevalent peripheral ground glass density of the bilateral lung.] | <a href="#">Comments</a> |

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT  
on Dec/10/2020

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Dec/10/2020 |
| 2. | Erroneous Visit |             |

**COVID-19 Illness Visit**

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

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
on Dec/10/2020

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**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 | [BR511S] |
| 5.b | Sample ID | [BR511T] |
| 5.c | Sample ID | [BS2S4T] |
| 5.d | Sample ID | [BS2S4V] |

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**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:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

**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:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

**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:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

| #  | Category      | AE Identifier | Adverse Event | Start Date          | Is the Adverse Event Still Ongoing              | Form Instance                   |
|----|---------------|---------------|---------------|---------------------|---|---------------------------------|
| 1. | ADVERSE EVENT | 1             | Anxiety       | Nov/21/2020 UNK:UNK | NO<br>End Date Time:<br><br>Mar/10/2021 UNK:UNK | <a href="#">Repeating Pages</a> |



Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1217

Subject No: 12171044

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Queries, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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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)  | [Anxiety]  |
| 4.  | Start Date Time:  | Nov/21/2020 UNK:UNK  |
| 5.  | Is the adverse event still ongoing?   | NO<br>End Date Time:<br>Mar/10/2021 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:   | NOT RELATED<br>If Not Related to study treatment(s), this event is due to:<br>OTHER<br>If Other, specify:<br>[related to the covid-19 disease] |
| 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   |

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**Visit:** Logs - Unscheduled

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**Site No:** 1217

**Subject No:** 12171044

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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|     |  |     |
|-----|--|-----|
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO  |
| 15. | Serious Adverse Event Number: For Pfizer Use Only                          | [ ] |

**Header Text:** C4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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

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**Header Text:** C4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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**Medication Error**

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

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**Header Text:** C4591001

**Visit:** Logs

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

| #  | Sponsor-Defined Identifier | Category for Medication | Concomitant Medications Pre-specified | Name of Medication   | Start Date  | Form Instance                   |
|----|----------------------------|-------------------------|---------------------------------------|----------------------|-------------|---------------------------------|
| 1. | 1                          | VACCINATIONS            | NO                                    | Influenza vaccine    | Dec/15/2020 | <a href="#">Repeating Pages</a> |
| 2. | 2                          | VACCINATIONS            | NO                                    | pneumococcal vaccine | Dec/15/2020 | <a href="#">Repeating Pages</a> |

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

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**Subject No:** 12171044

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

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

**Form Status:** Data Complete, Verified

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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**Concomitant Medications**

|    |   |                     |
|----|---|---------------------|
| 1. | What is the medication identifier?  | [1]                 |
| 2. | Category:   | VACCINATIONS        |
| 3. | Concomitant Medications<br>Pre-specified:   | NO                  |
| 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). | [Influenza vaccine] |
| 5. | Date:   | Dec/15/2020         |

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**Site No:** 1217

**Subject No:** 12171044

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

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

**Form Status:** Data Complete, Verified

**Site Name:** (1217) Kocaeli University Faculty of Medicine

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**Concomitant Medications**

|    |   |                        |
|----|---|------------------------|
| 1. | What is the medication identifier?  | [2]                    |
| 2. | Category:   | VACCINATIONS           |
| 3. | Concomitant Medications Pre-specified:  | NO                     |
| 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). | [pneumococcal vaccine] |
| 5. | Date:   | Dec/15/2020            |

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**Header Text:** C4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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



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**Visit:** Logs - Unscheduled

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

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**Subject No:** 12171044

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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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?  |     |

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**Header Text:** C4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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

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**Visit:** Logs - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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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:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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

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**Visit:** Logs - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171044

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**Form:** TRANSFUSIONS

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**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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

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**Header Text:** C4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Dec/03/2020

**Form:** DATE OF VISIT

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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**Date of Visit**

|    |                 |            |
|----|-----------------|------------|
| 1. | Date of Visit   | Dec/3/2020 |
| 2. | Erroneous Visit |            |

**Header Text:** C4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Dec/03/2020

**Form:** UNPLANNED VISIT

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Unplanned Assessments**

|    |             |                 |
|----|-------------|-----------------|
| 1. | Assessments | CONTACT OUTCOME |
|----|-------------|-----------------|

**Header Text:** C4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Dec/03/2020

**Form:** CONTACT OUTCOME - UNPLANNED

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Contact Outcome**

|    |                   |  |
|----|-------------------|--|
| 1. | Contact Type:     | TELEPHONE VISIT  |
| 2. | Was contact made? | YES<br>Date of Contact:<br>Dec/3/2020<br><br>Contact Outcome:<br>VISIT NOT REQUIRED, INVESTIGATOR DECISION |
| 3. | Comments:         | [ ]  |



**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

**Date of Visit**

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

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VITAL SIGNS - TEMP

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

**Form Status:** Not Started

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

**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? |     |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (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:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

**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:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

**Contact Outcome**

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

**Header Text:** C4591001

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

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

**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:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

**Informed Consent - Asymptomatic Surveillance**

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

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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



**Header Text:** C4591001

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

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

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

**Form Status:** Not Started

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

**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:** End of Treatment - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** DISPOSITION - TREATMENT

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Disposition - Treatment**

|    |   |                                      |
|----|---|--------------------------------------|
| 1. | Date of Completion/Discontinuation /Death : | Nov/10/2020                          |
| 2. | Phase of Disposition:                       | VACCINATION                          |
| 3. | Status:                                     | NO LONGER MEETS ELIGIBILITY CRITERIA |
| 4. | Specify Status:                             | [Exclusion criterion 5]              |

**Header Text:** C4591001

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

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Dec/30/2020 |
| 2. | Erroneous Visit |             |

**Header Text:** C4591001

**Visit:** Potential ReVax Initial Contact - Unscheduled **Form:** FURTHER VACCINATION CONFIRMATION

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

**Form Status:** Data Complete, Frozen

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

|    |   |  |
|----|---|--|
| 1. | Select appropriate response - Is participant willing to return for Vaccination 3? | Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible |
|----|---|--|

**Header Text:** C4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Data Complete, Verified

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Disposition - Follow-Up**

|    |   |   |
|----|---|---|
| 1. | Date of Completion/Discontinuation /Death : | Mar/4/2021  |
| 2. | Phase of Disposition:                       | FOLLOW-UP   |
| 3. | Status:                                     | WITHDRAWAL BY SUBJECT                                       |
| 4. | Specify Status:                             | [He withdrew from the study because he give up vaccinated.] |

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** TREATMENT UNBLINDED

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Treatment Unblinded**

|    |                                |   |
|----|--------------------------------|---|
| 1. | Date Treatment Unblinded :     | Dec/30/2020                                   |
| 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:** 1217

**Subject No:** 12171044

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

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Data Complete, Verified

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[Form Comments](#)

[eCRF Audit Trail History](#)

**Withdrawal Of Consent**

|    |                              |            |                          |
|----|------------------------------|------------|--------------------------|
| 1. | Withdrawal of Consent Date : | Mar/4/2021 | <a href="#">Comments</a> |
|----|------------------------------|------------|--------------------------|

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** DEATH DETAILS CODED

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[Form Comments](#)

[eCRF Audit Trail History](#)

**Death Details**

|    |   |                               |                          |
|----|---|-------------------------------|--------------------------|
| 1. | Date of Collection / Notification of Death: | Not Applicable<br>_____<br>// | <a href="#">Comments</a> |
|----|---|-------------------------------|--------------------------|

**Cause of Death**

|    |                        |                                |
|----|------------------------|--------------------------------|
| 2. | Cause of Death Status: | Not Applicable<br>_____        |
|    | Cause of Death:        | Not Applicable<br>_____<br>[ ] |



**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Subject Status**

|    |                     |              |
|----|---------------------|--------------|
| 1. | Subject Status      | DISCONTINUED |
| 2. | Subject Status Date | Mar/4/2021   |

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** CASEBOOK SIGNATURE FORM

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** CASEBOOK SIGNATURE FORM

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

[Audit Trail](#)

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

- CRF\_Sign

| Name       | Signature Meaning | Date                                      | Type | Action |
|------------|-------------------|---|------|--------|
| Sila Akhan | Approved          | Mar-12-2021 13:18:44 (UTC+03:00) Istanbul | BOOK | Signed |

**Affidavit:**

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

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

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

**Header Text:** C4591001

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

**Form Version:** 10-Oct-2020 16:00

**Site No:** 1217

**Subject No:** 12171044

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

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

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment        |
|------|---|---------------------|----------------|
| Form | Nov-04-2020 14:02:54 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Applicable |

**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** GENERAL MEDICAL HISTORY - Comments

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment        |
|------|---|---------------------|----------------|
| Form | Nov-04-2020 14:03:55 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Applicable |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment  |
|------|---|---------------------|----------|
| Form | Dec-10-2020 19:08:34 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done |

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment  |
|------|---|---------------------|----------|
| 1    | Dec-10-2020 19:08:34 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done |

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment  |
|------|---|---------------------|----------|
| 2    | Dec-10-2020 19:08:34 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done |



**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment  |
|------|---|---------------------|----------|
| 3    | Dec-10-2020 19:08:34 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done |

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment  |
|------|---|---------------------|----------|
| 4    | Dec-10-2020 19:08:34 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done |

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment  |
|------|---|---------------------|----------|
| 5    | Dec-10-2020 19:08:34 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done |

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment  |
|------|---|---------------------|----------|
| 6    | Dec-10-2020 19:08:34 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done |

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment  |
|------|---|---------------------|----------|
| 7    | Dec-10-2020 19:08:34 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done |

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment  |
|------|---|---------------------|----------|
| 8    | Dec-10-2020 19:08:34 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done |

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment  |
|------|---|---------------------|----------|
| 9    | Dec-10-2020 19:08:34 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done |

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment  |
|------|---|---------------------|----------|
| 10   | Dec-10-2020 19:08:34 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done |



**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** VACCINATION - Comments

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment  |
|------|---|---------------------|----------|
| 11   | Dec-10-2020 19:08:34 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done |

**Header Text:** C4591001

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

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

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment  |
|------|---|---------------------|--|
| Form | Jan-15-2021 15:14:56 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | The second vaccination could not administer to the subject due to Covid-19 disease. So the second vaccination diary did not completed. |
| Form | Jan-15-2021 13:30:29 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done   |
| Form | Jan-08-2021 12:59:33 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Applicable   |

**Header Text:** C4591001

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

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

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment        |
|------|---|---------------------|----------------|
| 1    | Jan-15-2021 13:30:29 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done       |
| 1    | Jan-08-2021 12:59:33 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Applicable |

**Header Text:** C4591001

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

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

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment        |
|------|---|---------------------|----------------|
| 2.a  | Jan-15-2021 13:30:29 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done       |
| 2.a  | Jan-08-2021 12:59:33 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Applicable |

**Header Text:** C4591001

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

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

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment        |
|------|---|---------------------|----------------|
| 2.b  | Jan-15-2021 13:30:29 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done       |
| 2.b  | Jan-08-2021 12:59:33 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Applicable |

**Header Text:** C4591001

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

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

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment        |
|------|---|---------------------|----------------|
| 2.c  | Jan-15-2021 13:30:29 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done       |
| 2.c  | Jan-08-2021 12:59:33 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Applicable |

**Header Text:** C4591001

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

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

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment        |
|------|---|---------------------|----------------|
| 2.d  | Jan-15-2021 13:30:29 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done       |
| 2.d  | Jan-08-2021 12:59:33 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Applicable |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

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

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

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment        |
|------|---|---------------------|----------------|
| 2.e  | Jan-15-2021 13:30:29 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done       |
| 2.e  | Jan-08-2021 12:59:33 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Applicable |



**Header Text:** C4591001

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

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

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment        |
|------|---|---------------------|----------------|
| 2 f  | Jan-15-2021 13:30:29 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done       |
| 2 f  | Jan-08-2021 12:59:33 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Applicable |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

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

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

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment        |
|------|---|---------------------|----------------|
| 2.g  | Jan-15-2021 13:30:29 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done       |
| 2.g  | Jan-08-2021 12:59:33 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Applicable |

**Header Text:** C4591001

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

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

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment        |
|------|---|---------------------|----------------|
| 2 h  | Jan-15-2021 13:30:29 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done       |
| 2 h  | Jan-08-2021 12:59:33 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Applicable |

**Header Text:** C4591001

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

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

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment        |
|------|---|---------------------|----------------|
| 3    | Jan-15-2021 13:30:29 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done       |
| 3    | Jan-08-2021 12:59:33 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Applicable |

**Header Text:** C4591001

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

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

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment        |
|------|---|---------------------|----------------|
| 4    | Jan-15-2021 13:30:29 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done       |
| 4    | Jan-08-2021 12:59:33 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Applicable |

**Header Text:** C4591001

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

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

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment        |
|------|---|---------------------|----------------|
| 5.a  | Jan-15-2021 13:30:29 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done       |
| 5.a  | Jan-08-2021 12:59:33 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Applicable |

**Header Text:** C4591001

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

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

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment        |
|------|---|---------------------|----------------|
| 5.b  | Jan-15-2021 13:30:29 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done       |
| 5.b  | Jan-08-2021 12:59:33 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Applicable |

**Header Text:** C4591001

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

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

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment        |
|------|---|---------------------|----------------|
| 5.c  | Jan-15-2021 13:30:29 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done       |
| 5.c  | Jan-08-2021 12:59:33 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Applicable |



**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - Comments

**Form Status:** Data Complete, Not Complete

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment   |
|------|---|---------------------|---|
| 3    | Jan-06-2021 15:33:13 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | “shortness of breath” is still ongoing, but “fever, new or increased muscle pain, new loss of taste or smell and sweating” were ended on 10 dec 2020. |
| 3    | Jan-06-2021 15:19:46 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | subject symptoms ongoing  |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                       | Comment   |
|------|---|----------------------------|---|
| 9    | Nov-19-2020 18:21:31 (UTC+03:00) Istanbul | Binnur Yildirim<br>(b) (4) | Test was performed at the site.Lab name is Kocaeli Universitesi Arastirma ve Uygulama Hsstanesi, Tibbi Mikrobiyoloji Laboratuvari. The lab has Turkey's Ministry of Health License. License no:438/03 |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment   |
|------|---|---------------------|---|
| 9    | Nov-24-2020 15:41:09 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Test was performed at the site.Lab name is Kocaeli Universitesi Arastirma ve Uygulama Hsstanesi, Tibbi Mikrobiyoloji Laboratuvari. The lab has Turkey's Ministry of Health License. License no:438/03 |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment        |
|------|---|---------------------|----------------|
| Form | Nov-18-2020 20:56:31 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) |                |
| Form | Nov-17-2020 15:08:35 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done       |
| Form | Nov-16-2020 11:58:01 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Applicable |
| Form | Nov-12-2020 17:09:03 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done       |

**Header Text:** C4591001

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

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

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment        |
|------|---|---------------------|----------------|
| 1    | Nov-18-2020 20:56:31 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) |                |
| 1    | Nov-17-2020 15:08:35 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done       |
| 1    | Nov-16-2020 11:58:01 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Applicable |
| 1    | Nov-12-2020 17:09:03 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done       |

**Header Text:** C4591001

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

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

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment        |
|------|---|---------------------|----------------|
| 2    | Nov-18-2020 20:56:31 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) |                |
| 2    | Nov-17-2020 15:08:35 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done       |
| 2    | Nov-16-2020 11:58:01 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Applicable |
| 2    | Nov-12-2020 17:09:03 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done       |

**Header Text:** C4591001

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

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

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment        |
|------|---|---------------------|----------------|
| 3    | Nov-18-2020 20:56:31 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) |                |
| 3    | Nov-17-2020 15:08:35 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done       |
| 3    | Nov-16-2020 11:58:01 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Applicable |
| 3    | Nov-12-2020 17:09:03 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done       |

**Header Text:** C4591001

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

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

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment        |
|------|---|---------------------|----------------|
| 4    | Nov-18-2020 20:56:31 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) |                |
| 4    | Nov-17-2020 15:08:35 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done       |
| 4    | Nov-16-2020 11:58:01 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Applicable |
| 4    | Nov-12-2020 17:09:03 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done       |



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** RESPIRATORY TREATMENT - Comments

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                       | Comment        |
|------|---|----------------------------|----------------|
| 3    | Nov-23-2020 15:43:28 (UTC+03:00) Istanbul | Binnur Yildirim<br>(b) (4) |                |
| 3    | Nov-16-2020 16:35:12 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6)        | Not Applicable |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** RESPIRATORY TREATMENT - Comments

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                       | Comment        |
|------|---|----------------------------|----------------|
| 5    | Nov-23-2020 15:43:46 (UTC+03:00) Istanbul | Binnur Yildirim<br>(b) (4) |                |
| 5    | Nov-16-2020 16:35:27 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6)        | Not Applicable |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** RESPIRATORY TREATMENT - Comments

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                       | Comment        |
|------|---|----------------------------|----------------|
| 6    | Nov-23-2020 15:44:18 (UTC+03:00) Istanbul | Binnur Yildirim<br>(b) (4) |                |
| 6    | Nov-16-2020 16:35:38 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6)        | Not Applicable |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** ILLNESS DETAILS - Comments

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment  |
|------|---|---------------------|----------|
| Form | Nov-16-2020 12:02:26 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) |          |
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**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** ILLNESS DETAILS - Comments

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

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| 2    | Nov-16-2020 12:02:26 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) |          |
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| 3    | Nov-16-2020 12:02:26 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) |          |
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**Form Version:** 17-Jul-2020 21:55

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**Site No:** 1217

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**Subject No:** 12171044

**Subject Initials:** ---

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

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| Form | Nov-23-2020 15:53:57 (UTC+03:00) Istanbul | Binnur Yildirim<br>(b) (4) |                |
| Form | Nov-16-2020 16:47:25 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6)        | Not Applicable |
| Form | Nov-16-2020 16:45:12 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6)        |                |
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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

**Form Version:** 10-Oct-2020 15:58

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

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**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

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

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| 5.a  | Nov-17-2020 15:28:02 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | grade-1, related to covid-19 |

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

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

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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** OXYGENATION PARAMETERS - Comments

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

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

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**Subject No:** 12171044

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

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| Form | Nov-23-2020 16:06:48 (UTC+03:00) Istanbul | Binnur Yildirim<br>(b) (4) |          |
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**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment  |
|------|---|---------------------|----------|
| 6    | Nov-16-2020 17:34:37 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) |          |
| 6    | Nov-13-2020 11:47:54 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** IMAGING - Comments

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment  |
|------|---|---------------------|----------|
| Form | Nov-16-2020 17:28:26 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) |          |
| Form | Nov-13-2020 11:47:27 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done |



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** IMAGING - Comments

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment  |
|------|---|---------------------|----------|
| 1    | Nov-16-2020 17:28:26 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) |          |
| 1    | Nov-13-2020 11:47:27 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** IMAGING - Comments

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment  |
|------|---|---------------------|----------|
| 2    | Nov-16-2020 17:28:26 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) |          |
| 2    | Nov-13-2020 11:47:27 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** IMAGING - Comments

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment  |
|------|---|---------------------|----------|
| 3    | Nov-16-2020 17:28:26 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) |          |
| 3    | Nov-13-2020 11:47:27 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** IMAGING - Comments

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment  |
|------|---|---------------------|----------|
| 4    | Nov-16-2020 17:28:26 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) |          |
| 4    | Nov-13-2020 11:47:27 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Done |

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** WITHDRAWAL OF CONSENT - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment        |
|------|---|---------------------|----------------|
| Form | Mar-06-2021 20:29:09 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) |                |
| Form | Jan-04-2021 14:20:05 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Applicable |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** Disposition

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** WITHDRAWAL OF CONSENT - Comments

**Form Status:** Data Complete, Verified

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment        |
|------|---|---------------------|----------------|
| 1    | Mar-06-2021 20:29:09 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) |                |
| 1    | Jan-04-2021 14:20:05 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Applicable |

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** DEATH DETAILS CODED - Comments

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment        |
|------|---|---------------------|----------------|
| Form | Jan-04-2021 14:20:22 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Applicable |

**Header Text:** C4591001

**Visit:** Disposition

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** DEATH DETAILS CODED - Comments

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Item | Date                                      | User                | Comment        |
|------|---|---------------------|----------------|
| 1    | Jan-04-2021 14:20:22 (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Not Applicable |



Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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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 |
|------------|-------------------|---|------|--------|
| Sila Akhan | Approved          | Mar-12-2021 13:18:44 (UTC+03:00) Istanbul | BOOK | Signed |

**Affidavit:**

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

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

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

|         |     |   |  |                                   |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Mar-12-2021 13:16:04 (UTC+03:00) Istanbul |  | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

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|------------|----------|---|------|--------|
| Sila Akhan | Approved | Mar-12-2021 13:01:49 (UTC+03:00) Istanbul | BOOK | Signed |
|------------|----------|---|------|--------|

**Affidavit:**

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

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

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

|         |     |   |  |                                   |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Mar-12-2021 12:16:43 (UTC+03:00) Istanbul |  | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|            |          |   |      |        |
|------------|----------|---|------|--------|
| Sila Akhan | Approved | Mar-06-2021 20:42:08 (UTC+03:00) Istanbul | BOOK | Signed |
|------------|----------|---|------|--------|

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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|         |     |   |  |                                   |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Mar-06-2021 20:29:09 (UTC+03:00) Istanbul |  | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|            |          |   |      |        |
|------------|----------|---|------|--------|
| Sila Akhan | Approved | Mar-05-2021 11:12:01 (UTC+03:00) Istanbul | BOOK | Signed |
|------------|----------|---|------|--------|

**Affidavit:**

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

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

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

|         |     |   |  |                                   |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Mar-05-2021 11:04:07 (UTC+03:00) Istanbul |  | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|            |          |   |      |        |
|------------|----------|---|------|--------|
| Sila Akhan | Approved | Feb-16-2021 12:39:01 (UTC+03:00) Istanbul | BOOK | Signed |
|------------|----------|---|------|--------|

**Affidavit:**

By my dated signature below, I, SilaAkhan, 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-16-2021 10:42:05 (UTC+03:00) Istanbul |  | Edit - All signatures invalidated |
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090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001**Visit:** Investigator Signature - Unscheduled**Form Version:** 22-Apr-2020 21:04**Site No:** 1217**Subject No:** 12171044**Generated By:** (b) (4)**Form:** CASEBOOK SIGNATURE FORM - Signature History**Form Status:** Data Complete, Signed, Verified**Site Name:** (1217) Kocaeli University Faculty of Medicine**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:11**Affidavit:**

N/A

|            |          |   |      |        |
|------------|----------|---|------|--------|
| Sila Akhan | Approved | Jan-18-2021 14:41:56 (UTC+03:00) Istanbul | BOOK | Signed |
|------------|----------|---|------|--------|

**Affidavit:**

By my dated signature below, I, SilaAkhan, 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-15-2021 13:30:29 (UTC+03:00) Istanbul |  | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|            |          |   |      |        |
|------------|----------|---|------|--------|
| Sila Akhan | Approved | Jan-13-2021 08:08:02 (UTC+03:00) Istanbul | BOOK | Signed |
|------------|----------|---|------|--------|

**Affidavit:**

By my dated signature below, I, SilaAkhan, 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.

|                 |     |   |  |                                   |
|-----------------|-----|---|--|-----------------------------------|
| Binnur Yildirim | N/A | Jan-11-2021 15:10:18 (UTC+03:00) Istanbul |  | Edit - All signatures invalidated |
|-----------------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|            |          |   |      |        |
|------------|----------|---|------|--------|
| Sila Akhan | Approved | Jan-08-2021 13:08:17 (UTC+03:00) Istanbul | BOOK | Signed |
|------------|----------|---|------|--------|

**Affidavit:**

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

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

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

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| (b) (6) | N/A | Jan-08-2021 12:58:20 (UTC+03:00) Istanbul |  | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|            |          |   |      |        |
|------------|----------|---|------|--------|
| Sila Akhan | Approved | Jan-07-2021 15:55:32 (UTC+03:00) Istanbul | BOOK | Signed |
|------------|----------|---|------|--------|

**Affidavit:**

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

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

|         |     |   |  |                                   |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Jan-06-2021 15:19:12 (UTC+03:00) Istanbul |  | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|         |          |   |      |        |
|---------|----------|---|------|--------|
| (b) (6) | Approved | Jan-05-2021 15:11:01 (UTC+03:00) Istanbul | BOOK | Signed |
|---------|----------|---|------|--------|

**Affidavit:**

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

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

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

|         |     |   |  |                                   |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Jan-05-2021 13:56:02 (UTC+03:00) Istanbul |  | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|            |          |   |      |        |
|------------|----------|---|------|--------|
| Sila Akhan | Approved | Jan-04-2021 14:55:02 (UTC+03:00) Istanbul | BOOK | Signed |
|------------|----------|---|------|--------|

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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

|                 |     |   |  |                                   |
|-----------------|-----|---|--|-----------------------------------|
| Binnur Yildirim | N/A | Dec-29-2020 13:57:36 (UTC+03:00) Istanbul |  | Edit - All signatures invalidated |
|-----------------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|            |          |   |      |        |
|------------|----------|---|------|--------|
| Sila Akhan | Approved | Dec-16-2020 14:46:36 (UTC+03:00) Istanbul | BOOK | Signed |
|------------|----------|---|------|--------|

**Affidavit:**

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

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|         |     |   |  |                                   |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Dec-15-2020 15:34:17 (UTC+03:00) Istanbul |  | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|            |          |   |      |        |
|------------|----------|---|------|--------|
| Sila Akhan | Approved | Dec-13-2020 12:40:57 (UTC+03:00) Istanbul | BOOK | Signed |
|------------|----------|---|------|--------|

**Affidavit:**

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

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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 18:38:25 (UTC+03:00) Istanbul |  | Edit - All signatures invalidated |
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090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

**Affidavit:**

N/A

|            |          |   |      |        |
|------------|----------|---|------|--------|
| Sila Akhan | Approved | Dec-09-2020 16:21:21 (UTC+03:00) Istanbul | BOOK | Signed |
|------------|----------|---|------|--------|

**Affidavit:**

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

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|                 |     |   |  |                                   |
|-----------------|-----|---|--|-----------------------------------|
| Binnur Yildirim | N/A | Dec-06-2020 17:18:43 (UTC+03:00) Istanbul |  | Edit - All signatures invalidated |
|-----------------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|            |          |   |      |        |
|------------|----------|---|------|--------|
| Sila Akhan | Approved | Dec-03-2020 14:19:27 (UTC+03:00) Istanbul | BOOK | Signed |
|------------|----------|---|------|--------|

**Affidavit:**

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

|                 |     |   |  |                                   |
|-----------------|-----|---|--|-----------------------------------|
| Binnur Yildirim | N/A | Dec-03-2020 08:44:57 (UTC+03:00) Istanbul |  | Edit - All signatures invalidated |
|-----------------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|            |          |   |      |        |
|------------|----------|---|------|--------|
| Sila Akhan | Approved | Dec-02-2020 20:39:46 (UTC+03:00) Istanbul | BOOK | Signed |
|------------|----------|---|------|--------|

**Affidavit:**

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

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090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

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

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

|         |     |   |  |                                   |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Nov-25-2020 11:32:01 (UTC+03:00) Istanbul |  | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|            |          |   |      |        |
|------------|----------|---|------|--------|
| Sila Akhan | Approved | Nov-25-2020 09:26:12 (UTC+03:00) Istanbul | BOOK | Signed |
|------------|----------|---|------|--------|

**Affidavit:**

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

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

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

|         |     |   |  |                                   |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Nov-18-2020 16:06:52 (UTC+03:00) Istanbul |  | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

**Affidavit:**

N/A

|            |          |   |      |        |
|------------|----------|---|------|--------|
| Sila Akhan | Approved | Nov-18-2020 09:29:28 (UTC+03:00) Istanbul | BOOK | Signed |
|------------|----------|---|------|--------|

**Affidavit:**

By my dated signature below, I, SilaAkhan, 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.

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** COHORT\_SELECTION - eCRF Audit Trail History

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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*1. Select appropriate response - Protocol version*

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Nov-04-2020 14:01:58<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(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        |
|--|-----------------|---------------------|---------------------------------------|---------------|
| Nov-04-2020 14:01:58<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>STAGE 3 COHORTS | Initial Entry |



**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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*I. Consent Was:*

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-04-2020 14:02:09<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>OBTAINED<br>Date Written Consent Obtained<br><br>Nov/4/2020 | Initial Entry |

Header Text: C4591001

Visit: COHORT\_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Subject ID**

| Date   | Location        | User                    | Value                          | Reason                         |
|--|-----------------|-------------------------|--------------------------------|--------------------------------|
| Nov-04-2020 14:01:48<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>12171044 | Item copied from previous form |

**2. Birth Date:**

| Date   | Location        | User                    | Value                               | Reason           |
|--|-----------------|-------------------------|-------------------------------------|------------------|
| Nov-04-2020 14:01:45<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>(b) (6) /1985 | Enrollment Entry |

**3. Sex:**

| Date   | Location        | User                | Value                      | Reason        |
|--|-----------------|---------------------|----------------------------|---------------|
| Nov-04-2020 14:02:30<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>MALE | Initial Entry |

**4. Ethnicity:**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-04-2020 14:02:30<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN | Initial Entry |

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

| Date   | Location        | User                | Value                       | Reason        |
|--|-----------------|---------------------|-----------------------------|---------------|
| Nov-04-2020 14:02:30<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>WHITE | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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*1. Date of Visit*

| Date   | Location        | User                | Value                            | Reason        |
|--|-----------------|---------------------|----------------------------------|---------------|
| Nov-04-2020 14:02:45<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/4/2020 | Initial Entry |

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:52

Site No: 1217

Subject No: 12171044

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Date of Completion/Discontinuation/Death**

| Date   | Location        | User                | Value                            | Reason        |
|--|-----------------|---------------------|----------------------------------|---------------|
| Nov-04-2020 14:03:22<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/4/2020 | Initial Entry |

**2. Phase of Disposition:**

| Date   | Location        | User                    | Value                           | Reason        |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Nov-04-2020 14:03:22<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SCREENING | Initial Entry |

**3. Status:**

| Date   | Location        | User                | Value                           | Reason        |
|--|-----------------|---------------------|---------------------------------|---------------|
| Nov-04-2020 14:03:22<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>COMPLETED | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** HIV STATUS - eCRF Audit Trail History

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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*1. Select appropriate response - What is the subject HIV status?*

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-04-2020 14:04:11<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(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: 10-Oct-2020 16:04

Site No: 1217

Subject No: 12171044

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Date:**

| Date   | Location        | User                | Value                            | Reason        |
|--|-----------------|---------------------|----------------------------------|---------------|
| Nov-04-2020 14:04:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>Nov/4/2020 | Initial Entry |

**2. Weight:**

| Date   | Location        | User                | Value                      | Reason        |
|--|-----------------|---------------------|----------------------------|---------------|
| Nov-04-2020 14:04:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>97.0 | Initial Entry |

**3. Unit:**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-04-2020 14:04:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>kg | Initial Entry |

**4. Height:**

| Date   | Location        | User                | Value                       | Reason        |
|--|-----------------|---------------------|-----------------------------|---------------|
| Nov-04-2020 14:04:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>185.0 | Initial Entry |

**5. Unit:**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-04-2020 14:04:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>cm | Initial Entry |

**6. Body Mass Index:**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Nov-04-2020 14:04:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>28.3 | Initial Entry |

**7.a**

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

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 10-Oct-2020 16:04

Site No: 1217

Subject No: 12171044

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

|  |                 |                     |   |               |
|--|-----------------|---------------------|---|---------------|
| Nov-04-2020 14:04:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Record Identifier::</b> 1<br><b>Temperature:</b> 36.4<br><b>Temperature Unit:</b> C<br><b>Temperature Location:</b> FOREHEA<br>: D | Initial Entry |
|--|-----------------|---------------------|---|---------------|

**7.a Record Identifier:**

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Nov-04-2020 14:04:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>1 | Initial Entry |

**7.a Temperature:**

| Date   | Location        | User                | Value                      | Reason        |
|--|-----------------|---------------------|----------------------------|---------------|
| Nov-04-2020 14:04:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>36.4 | Initial Entry |

**7.a Unit:**

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Nov-04-2020 14:04:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>C | Initial Entry |

**7.a Temperature Location:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Nov-04-2020 14:04:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>FOREHEAD | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** RANDOMIZATION - eCRF Audit Trail History

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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**1. Randomization Date :**

| Date   | Location        | User                | Value                            | Reason        |
|--|-----------------|---------------------|----------------------------------|---------------|
| Nov-04-2020 15:44:01<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/4/2020 | Initial Entry |

**2. Randomization Number:**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Nov-04-2020 15:44:01<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>115479 | Initial Entry |



**Header Text:** C4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1217**Site Name:** (1217) Kocaeli University Faculty of Medicine**Subject No:** 12171044**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Nov-04-2020 15:44:42<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                       | Reason        |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Nov-04-2020 15:44:42<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value  | Reason   |
|--|-----------------|---------------------------|--|--|
| Nov-04-2020 15:45:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted   | Close Auto Query   |
| Nov-04-2020 15:44:42<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate   | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Nov-04-2020 15:44:42<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Nov/4/2020 | Initial Entry  |

**5.a**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-04-2020 15:45:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BPZ97B | Initial Entry |

**5.a Sample ID**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Nov-04-2020 15:45:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BPZ97B | Initial Entry |

**5.b**

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: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-04-2020 15:45:12<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID: BPZ97C</b> | Initial Entry |

**5.b Sample ID**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Nov-04-2020 15:45:12<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BPZ97C | Initial Entry |

**5.c**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-19-2020 16:09:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID: BS2S65</b> | Initial Entry |

**5.c Sample ID**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Nov-19-2020 16:09:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BS2S65 | Initial Entry |

**5.d**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-19-2020 16:09:56<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID: BS2S66</b> | Initial Entry |

**5.d Sample ID**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Nov-19-2020 16:09:56<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BS2S66 | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1217**Site Name:** (1217) Kocaeli University Faculty of Medicine**Subject No:** 12171044**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Nov-04-2020 15:45:32<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Nov-04-2020 15:45:32<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value  | Reason   |
|--|-----------------|---------------------------|--|--|
| Nov-04-2020 15:45:48<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted   | Close Auto Query   |
| Nov-04-2020 15:45:32<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate   | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Nov-04-2020 15:45:32<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Nov/4/2020 | Initial Entry  |

**5.a**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-04-2020 15:45:48<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BPZ978 | Initial Entry |

**5.a Sample ID**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Nov-04-2020 15:45:48<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BPZ978 | Initial Entry |

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1217

Subject No: 12171044

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Was there a temporary delay of vaccination?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-04-2020 15:44:24<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>NO | Initial Entry |

**2. Treatment Name**

| Date   | Location        | User                    | Value                                 | Reason        |
|--|-----------------|-------------------------|---------------------------------------|---------------|
| Nov-04-2020 15:44:24<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>BLINDED THERAPY | Initial Entry |

**3. Formulation:**

| Date   | Location        | User                    | Value                           | Reason        |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Nov-04-2020 15:44:24<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>INJECTION | Initial Entry |

**4. Dose Date Time:**

| Date   | Location        | User                | Value                                  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-04-2020 15:44:24<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>Nov/4/2020 14:20 | Initial Entry |

**5. Anatomical Location:**

| Date   | Location        | User                    | Value                                | Reason        |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Nov-04-2020 15:44:24<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>DELTOID MUSCLE | Initial Entry |

**6. Body Side:**

| Date   | Location        | User                | Value                      | Reason        |
|--|-----------------|---------------------|----------------------------|---------------|
| Nov-04-2020 15:44:24<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>LEFT | Initial Entry |

**7. Route:**

| Date   | Location        | User                    | Value                               | Reason        |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Nov-04-2020 15:44:24<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>INTRAMUSCULAR | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** VACCINATION - eCRF Audit Trail History

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

**10. Timeframe Subject Was Observed**

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-04-2020 15:44:24<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>THE PROTOCOL SPECIFIED OBSER<br>VATION 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-04-2020 15:44:24<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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*1. Select appropriate response - Reactogenicity diary collection*

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-04-2020 14:05:36<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES - REACTOGENICITY E-DIARY<br>COLLECTED FOR THIS SUBJECT | Initial Entry |

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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***1. Date of Visit***

| Date   | Location                                  | User                      | Value                             | Reason   |
|--|---|---------------------------|-----------------------------------|--|
| Dec-15-2020<br>11:41:40<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | Annam Sireesha<br>(b) (4) | Query 1: Closed                   | Closed as per site response, updated PD tracker for clinical review  |
| Dec-14-2020<br>15:52:30<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)       | Query 1: Answered                 | data is correct the visit 2 was postponed due to covid-19 treatment.   |
| Dec-14-2020<br>08:33:07<br>(UTC+03:00)<br>Istanbul | 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 13 days from V1_DAY1_VAX1_L Dose Date. Please verify and update. Else, confirm in query response appropriately. (b) (4) |
| Dec-10-2020<br>18:40:15<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>Dec/10/2020 | Initial Entry  |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001**Visit:** V2\_VAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1217**Site Name:** (1217) Kocaeli University Faculty of Medicine**Subject No:** 12171044**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Dec-10-2020 18:45:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.a**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Dec-10-2020 18:56:32<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptom::</b><br>FE<br>VE<br>R<br><br>Were fever or systemic symptom<br>s present on the last day the Sub<br>ject Diary was completed?: | Initial Entry |
| Dec-10-2020 18:45:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptom::</b><br>FE<br>VE<br>R<br><br>Were fever or systemic symptom<br>s present on the last day the Sub<br>ject Diary was completed?: | Initial Entry |

**2.a Symptom:**

| Date   | Location        | User                | Value                       | Reason        |
|--|-----------------|---------------------|-----------------------------|---------------|
| Dec-10-2020 18:45:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>FEVER | Initial Entry |

**2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Dec-10-2020 18:56:32<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.b**

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



Header Text: C4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
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Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |                 |                     |  |                     |
|--|-----------------|---------------------|--|---------------------|
| Dec-15-2020 15:34:17<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <p><b>Data Entry:</b></p> <p><b>Symptom::</b> FATIGUE</p> <p><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> YES</p> <p>Ongoing?</p> <p>YES</p> <p>S</p>                              | Changed Information |
| Dec-10-2020 18:45:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <p><b>Data Entry:</b></p> <p><b>Symptom::</b> FATIGUE</p> <p><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> YES</p> <p>Ongoing?</p> <p>NO</p> <p>Stop Date:</p> <p>Nov /30/ 2020</p> | Initial Entry       |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
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Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

2.b Symptom:

| Date   | Location        | User                | Value                         | Reason        |
|--|-----------------|---------------------|-------------------------------|---------------|
| Dec-10-2020 18:45:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>FATIGUE | Initial Entry |

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date   | Location        | User                | Value  | Reason              |
|--|-----------------|---------------------|--|---------------------|
| Dec-15-2020 15:34:17<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES<br>Ongoing?<br><br>YES                                     | Changed Information |
| Dec-10-2020 18:45:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES<br>Ongoing?<br><br>NO<br><br>Stop Date:<br><br>Nov/30/2020 | Initial Entry       |

2.c

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Dec-10-2020 18:45:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptom::</b><br><br>HEA<br>DAC<br>HE<br><br><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?</b><br>NO<br>:<br>: | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

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Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

2.c Symptom:

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Dec-10-2020 18:45:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>HEADACHE | Initial Entry |

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Dec-10-2020 18:45:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>NO | Initial Entry |

2.d

| Date   | Location        | User                | Value   | Reason              |
|--|-----------------|---------------------|---|---------------------|
| Dec-15-2020 15:34:42<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>Symptom:: CHILLS<br>Were fever or systemic sy YES<br>mptoms present on the la Ongoing<br>st day the Subject Diary ?<br>was completed?: NO<br>Stop<br>Date:<br>Dec/<br>10/2<br>020     | Changed Information |
| Dec-10-2020 18:45:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>Symptom:: CHILLS<br>Were fever or systemic sy YES<br>mptoms present on the la Ongoing<br>st day the Subject Diary ?<br>was completed?: NO<br>Stop<br>Date:<br>Nov<br>/30/<br>202<br>0 | Initial Entry       |

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Header Text: C4591001

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Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

2.d Symptom:

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Dec-10-2020 18:45:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>CHILLS | Initial Entry |

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date   | Location        | User                | Value  | Reason              |
|--|-----------------|---------------------|--|---------------------|
| Dec-15-2020 15:34:42<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES<br>Ongoing?<br><br>NO<br><br>Stop Date:<br><br>Dec/10/2020 | Changed Information |
| Dec-10-2020 18:45:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES<br>Ongoing?<br><br>NO<br><br>Stop Date:<br><br>Nov/30/2020 | Initial Entry       |

2.e

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Dec-10-2020 18:45:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptom::</b> VO<br>MITI<br>NG<br><br><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

**2.e Symptom:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Dec-10-2020 18:45:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>VOMITING | Initial Entry |

**2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Dec-10-2020 18:45:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.f**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Dec-10-2020 18:45:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptom::</b> DIA<br>RRH<br>EA<br><br><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO | Initial Entry |

**2.f Symptom:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Dec-10-2020 18:45:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>DIARRHEA | Initial Entry |

**2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Dec-10-2020 18:45:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2.g**

| Date   | Location        | User                | Value   | Reason              |
|--|-----------------|---------------------|---|---------------------|
| Dec-15-2020 15:35:01<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptom::</b> NEW OR WORSENERED MUCLE PAIN | Changed Information |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|   |                 |                  |  |               |
|---|-----------------|------------------|--|---------------|
|   |                 |                  | <p>Were fever or systemi c symptoms present o n the last day the Sub ject Diary was compl eted?:</p> <p>YES Ongoing?</p> <p>NO</p> <p>Stop Date:</p> <p>Dec/10/2020</p>  |               |
| Dec-10-2020 18:45:00 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6) | <p><b>Data Entry:</b></p> <p><b>Symptom::</b> NEW OR WORSENEDEDMUSCLE PAIN</p> <p>Were fever or systemi c symptoms present o n the last day the Sub ject Diary was compl eted?:</p> <p>YES Ongoing?</p> <p>NO</p> <p>Stop Date:</p> <p>Nov/30/2020</p> | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

2.g Symptom:

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Dec-10-2020 18:45:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NEW OR WORSENERED MUSCLE PAIN | Initial Entry |

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date   | Location        | User                | Value  | Reason              |
|--|-----------------|---------------------|--|---------------------|
| Dec-15-2020 15:35:01<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES<br>Ongoing?<br><br>NO<br><br>Stop Date:<br><br>Dec/10/2020 | Changed Information |
| Dec-10-2020 18:45:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES<br>Ongoing?<br><br>NO<br><br>Stop Date:<br><br>Nov/30/2020 | Initial Entry       |

2.h

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Dec-10-2020 18:56:32<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptom::</b><br><br>NEW OR WORSENERED JOINT PAIN<br><br><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b><br><br>NO | Initial Entry |
| Dec-10-2020 18:45:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptom::</b><br><br>NEW OR WORSENERED JOINT PAIN   | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

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Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | Were fever or systemic symptoms present on the last day the Subject Diary was completed?: |  |
|--|--|--|---|--|

2.h Symptom:

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Dec-10-2020 18:45:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NEW OR WORSENERD JOINT PAIN | Initial Entry |

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Dec-10-2020 18:56:32<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

3. Injection Site Location:

| Date   | Location        | User                    | Value                                | Reason        |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Dec-10-2020 18:45:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DELTOID MUSCLE | Initial Entry |

4. Injection Site Body Side:

| Date   | Location        | User                | Value                      | Reason        |
|--|-----------------|---------------------|----------------------------|---------------|
| Dec-10-2020 18:56:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>LEFT | Initial Entry |

5.a

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Dec-10-2020 18:45:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Injection Site Reaction::</b> RED<br>NES<br>S<br><br><b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO | Initial Entry |

5.a Injection Site Reaction:

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

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)



Header Text: C4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |                 |                     |                               |               |
|--|-----------------|---------------------|-------------------------------|---------------|
| Dec-10-2020 18:45:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>REDNESS | Initial Entry |
|--|-----------------|---------------------|-------------------------------|---------------|

5.a Were injection site reactions present on the last day the Subject Diary was completed?

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Dec-10-2020 18:45:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

5.b

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Dec-10-2020 18:45:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Injection Site Reaction:: SWE<br>LLIN<br>G<br><br>Were injection site reactions p NO<br>resent on the last day the Subj<br>ect Diary was completed?: | Initial Entry |

5.b Injection Site Reaction:

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Dec-10-2020 18:45:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>SWELLING | Initial Entry |

5.b Were injection site reactions present on the last day the Subject Diary was completed?

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Dec-10-2020 18:45:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

5.c

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Dec-10-2020 18:45:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Injection Site Reaction:: PAIN AT<br>INJECTI<br>ON SITE | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |   |    |
|--|--|--|---|----|
|  |  |  | Were injection site reactions present on the last day the Subject Diary was completed?: | NO |
|--|--|--|---|----|

**5.c Injection Site Reaction:**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Dec-10-2020 18:45:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>PAIN AT INJECTION SITE | Initial Entry |

**5.c Were injection site reactions present on the last day the Subject Diary was completed?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Dec-10-2020 18:45:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 10-Dec-2020 02:27

Site No: 1217

Subject No: 12171044

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Date:**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Dec-10-2020 18:45:22<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Dec/10/2020 | Initial Entry |

**2.a**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Dec-10-2020 18:45:22<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Record Identifier::</b> 1<br><b>Temperature:</b> 36.4<br><b>Temperature Unit:</b> C<br><b>Temperature Location:</b> FOREHEA<br>D | Initial Entry |

**2.a Record Identifier:**

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Dec-10-2020 18:45:22<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>1 | Initial Entry |

**2.a Temperature:**

| Date   | Location        | User                | Value                      | Reason        |
|--|-----------------|---------------------|----------------------------|---------------|
| Dec-10-2020 18:45:22<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>36.4 | Initial Entry |

**2.a Unit:**

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Dec-10-2020 18:45:22<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>C | Initial Entry |

**2.a Temperature Location:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Dec-10-2020 18:45:22<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>FOREHEAD | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Dec-10-2020 18:57:03<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Dec-10-2020 18:57:03<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value   | Reason   |
|--|-----------------|---------------------------|---|--|
| Dec-11-2020 12:20:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted  | Close Auto Query   |
| Dec-10-2020 18:57:03<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate  | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Dec-10-2020 18:57:03<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(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 12:20:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Sample ID: BPZ9CM | Initial Entry |

**5.a Sample ID**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Dec-11-2020 12:20:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BPZ9CM | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 10-Dec-2020 02:26

Site No: 1217

Subject No: 12171044

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Was there a temporary delay of vaccination?**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Dec-10-2020 19:08:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**2. Treatment Name**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Dec-10-2020 19:08:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**3. Formulation:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Dec-10-2020 19:08:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**4. Dose Date Time:**

| Date   | Location                                  | User                 | Value                          | Reason   |
|--|---|----------------------|--------------------------------|--|
| Mar-12-2021 20:21:15<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)  | Query 1: Answered              | The second dose could not be administered because the volunteer had covid-19 disease after the 1st dose and was hospitalized.  |
| Mar-12-2021 18:23:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY<br>(b) (4) | Query 1: Opened                | DMW7692142;Randomization number is recorded and the final disposition date is present on the Disposition - Follow-up eCRF, but there is no dosing date present on the Treatment eCRF. Please review and update as appropriate. |
| Dec-10-2020 19:08:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)  | <b>Data Entry:</b><br>Not Done | Initial Entry  |

**5. Anatomical Location:**

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 10-Dec-2020 02:26

Site No: 1217

Subject No: 12171044

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Dec-10-2020 19:08:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>Not Done | Initial Entry |

**6. Body Side:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Dec-10-2020 19:08:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>Not Done | Initial Entry |

**7. Route:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Dec-10-2020 19:08:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>Not Done | Initial Entry |

**8. Actual Dose:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Dec-10-2020 19:08:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>Not Done | Initial Entry |

**9. Unit:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Dec-10-2020 19:08:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>Not Done | Initial Entry |

**10. Timeframe Subject Was Observed**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Dec-10-2020 19:08:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>Not Done | Initial Entry |

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

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Dec-10-2020 19:08:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>Not Done | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

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

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

**Site No:** 1217

**Subject No:** 12171044

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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*1. Date of Visit*

| Date   | Location        | User                              | Value                            | Reason        |
|--|-----------------|-----------------------------------|----------------------------------|---------------|
| Jan-08-2021 12:58:20<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)<br>[REDACTED] | <b>Data Entry:</b><br>Jan/8/2021 | Initial Entry |

**Header Text:** C4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:03**Form Status:** Data Complete, Verified**Site No:** 1217**Site Name:** (1217) Kocaeli University Faculty of Medicine**Subject No:** 12171044**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

| Date   | Location        | User                       | Value                                | Reason   |
|--|-----------------|----------------------------|--------------------------------------|--|
| Jan-15-2021 13:30:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br>Not Done       | Initial Entry  |
| Jan-15-2021 11:46:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | Query 1: Closed                      | As per site confirmation - updated PD tracker  |
| Jan-11-2021 11:47:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | Query 1: Answered                    | The second vaccination could not administer to the subject due to Covid-19 disease. So the second vaccination diary did not completed.   |
| Jan-11-2021 09:50:24<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | Query 1: Opened                      | PDQ: Vaccination is given, however FORM level comment added as NOT Applicable added on 'Vaccination Symptoms Diary-Symptom Resolved Dates' CRF. Please review and update else clarify. |
| Jan-08-2021 12:59:33<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br>Not Applicable | Initial Entry  |

**2.a**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Jan-15-2021 13:30:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptom::</b><br><br><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> | Initial Entry |
| Jan-08-2021 12:59:33                         | ACV0PFEINFP6000 | (b) (4), (b) (6)    | <b>Data Entry:</b>   | Initial Entry |



Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|                      |  |                  |  |                                      |
|----------------------|--|------------------|--|--------------------------------------|
| (UTC+03:00) Istanbul |  | (b) (4), (b) (6) | Symptom::<br><br>Were fever or systemic symptoms present on the last day the Subject Diary was completed?: | Not Applicable<br><br>Not Applicable |
|----------------------|--|------------------|--|--------------------------------------|

2.a Symptom:

| Date   | Location        | User             | Value                                | Reason        |
|--|-----------------|------------------|--------------------------------------|---------------|
| Jan-08-2021 12:59:33<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date   | Location                                  | User                       | Value                                | Reason   |
|--|---|----------------------------|--------------------------------------|--|
| Jan-15-2021 13:30:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000                           | (b) (4), (b) (6)           | <b>Data Entry:</b><br>Not Done       | Initial Entry  |
| Jan-12-2021 07:52:06<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000                           | (b) (4), (b) (6)           | Query 1:<br>Closed                   | Response satisfies query   |
| Jan-11-2021 11:47:40<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000                           | Binnur Yildirim<br>(b) (4) | Query 1:<br>Answered                 | The second vaccination could not administer to the subject due to Covid-19 disease. So the second vaccination diary did not completed.           |
| Jan-11-2021 11:05:12<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY<br>(b) (4)       | Query 1:<br>Opened                   | DMW6739227;Symptoms Occur? are not expected to be Unknown or Not Applicable. Please review and update appropriately for all symptoms or clarify. |
| Jan-08-2021 12:59:33<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000                           | (b) (4), (b) (6)           | <b>Data Entry:</b><br>Not Applicable | Initial Entry  |

2.b

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Jan-15-2021 13:30:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptom::</b> Not<br>Applicable<br><br><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> Not Done       | Initial Entry |
| Jan-08-2021 12:59:33<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptom::</b> Not<br>Applicable<br><br><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> Not Applicable | Initial Entry |

2.b Symptom:

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Jan-08-2021 12:59:33<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Jan-15-2021 13:30:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done       | Initial Entry |
| Jan-08-2021 12:59:33<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

2.c

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Jan-15-2021 13:30:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptom::</b> Not<br>Applicable | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|   |                 |                  |   |                |
|---|-----------------|------------------|---|----------------|
|   |                 |                  | Were fever or systemic symptoms present on the last day the Subject Diary was completed?: | Not Done       |
| Jan-08-2021 12:59:33 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptom::</b>  | Not Applicable |
|   |                 |                  | Were fever or systemic symptoms present on the last day the Subject Diary was completed?: | Not Applicable |

2.c Symptom:

| Date                                      | Location        | User             | Value                                | Reason        |
|---|-----------------|------------------|--------------------------------------|---------------|
| Jan-08-2021 12:59:33 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date                                      | Location        | User             | Value                                | Reason        |
|---|-----------------|------------------|--------------------------------------|---------------|
| Jan-15-2021 13:30:29 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done       | Initial Entry |
| Jan-08-2021 12:59:33 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

2.d

| Date                                      | Location        | User             | Value   | Reason         |
|---|-----------------|------------------|---|----------------|
| Jan-15-2021 13:30:29 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptom::</b>  | Not Applicable |
|   |                 |                  | Were fever or systemic symptoms present on the last day the Subject Diary was completed?: | Not Done       |
| Jan-08-2021 12:59:33 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptom::</b>  | Not Applicable |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |   |                |
|--|--|--|---|----------------|
|  |  |  | Were fever or systemic symptoms present on the last day the Subject Diary was completed?: | Not Applicable |
|--|--|--|---|----------------|

2.d Symptom:

| Date                                      | Location        | User             | Value                                | Reason        |
|---|-----------------|------------------|--------------------------------------|---------------|
| Jan-08-2021 12:59:33 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date                                      | Location        | User             | Value                                | Reason        |
|---|-----------------|------------------|--------------------------------------|---------------|
| Jan-15-2021 13:30:29 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Done       | Initial Entry |
| Jan-08-2021 12:59:33 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

2.e

| Date                                      | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Jan-15-2021 13:30:29 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptom::</b><br>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:<br>Not Applicable | Initial Entry |
| Jan-08-2021 12:59:33 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptom::</b><br>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:<br>Not Applicable | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

2.e Symptom:

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Jan-08-2021 12:59:33<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Jan-15-2021 13:30:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done       | Initial Entry |
| Jan-08-2021 12:59:33<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

2.f

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Jan-15-2021 13:30:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptom::</b><br>Not Applicable<br><br><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b><br>Not Done       | Initial Entry |
| Jan-08-2021 12:59:33<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptom::</b><br>Not Applicable<br><br><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b><br>Not Applicable | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

2.f Symptom:

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Jan-08-2021 12:59:33<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Jan-15-2021 13:30:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done       | Initial Entry |
| Jan-08-2021 12:59:33<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

2.g

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Jan-15-2021 13:30:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptom::</b><br>Not Applicable<br><br><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b><br>Not Done       | Initial Entry |
| Jan-08-2021 12:59:33<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptom::</b><br>Not Applicable<br><br><b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b><br>Not Applicable | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

2.g Symptom:

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Jan-08-2021 12:59:33<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Jan-15-2021 13:30:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done       | Initial Entry |
| Jan-08-2021 12:59:33<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

2.h

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Jan-15-2021 13:30:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptom::</b><br>Not<br>Appli<br>cable<br><br><b>Were fever or systemic sympt<br/>oms present on the last day th<br/>e Subject Diary was complete<br/>d?:</b><br>Not<br>Done           | Initial Entry |
| Jan-08-2021 12:59:33<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptom::</b><br>Not<br>Appli<br>cable<br><br><b>Were fever or systemic sympt<br/>oms present on the last day th<br/>e Subject Diary was complete<br/>d?:</b><br>Not<br>Appli<br>cable | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

**2.h Symptom:**

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Jan-08-2021 12:59:33<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

**2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Jan-15-2021 13:30:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done       | Initial Entry |
| Jan-08-2021 12:59:33<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

**3. Injection Site Location:**

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Jan-15-2021 13:30:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done       | Initial Entry |
| Jan-08-2021 12:59:33<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

**4. Injection Site Body Side:**

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Jan-15-2021 13:30:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done       | Initial Entry |
| Jan-08-2021 12:59:33<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

**5.a**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Jan-15-2021 13:30:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Injection Site Reaction::</b> Not Applicable | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)



Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |                 |                     |   |               |
|--|-----------------|---------------------|---|---------------|
|  |                 |                     | Were injection site reactions present on the last day the Subject Diary was completed?:   |               |
| Jan-08-2021 12:59:33<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Injection Site Reaction:</b> Not Applicable<br><br><b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> Not Applicable | Initial Entry |

5.a Injection Site Reaction:

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Jan-08-2021 12:59:33<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

5.a Were injection site reactions present on the last day the Subject Diary was completed?

| Date   | Location                                  | User                 | Value                          | Reason   |
|--|---|----------------------|--------------------------------|--|
| Jan-16-2021 00:12:20<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY<br>(b) (4) | Query 1: Closed                | Auto closed by Validation Check: VC_FAVSD011_03  |
| Jan-15-2021 13:37:37<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)  | Query 1: Answered              | The second vaccination could not administer to the subject due to Covid-19 disease. So the second vaccination diary did not completed. |
| Jan-15-2021 13:30:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)  | <b>Data Entry:</b><br>Not Done | Initial Entry  |
| Jan-15-2021 08:58:47<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000                           | (b) (4), (b) (6)     | Query 1: Reissued: Opened      | DM : Reactions Occur? are not expected to be Unknown or Not Applicable. Please review and update appropriately . Else, clarify         |
| Jan-13-2021 09:00:04<br>(UTC+03:00)          | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)  | Query 1: Answered              | The second injection was not done however the diary was not completed  |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |   |                            |                                      |   |
|--|---|----------------------------|--------------------------------------|---|
| Istanbul   |   |                            |                                      | because of that.  |
| Jan-12-2021<br>13:25:36<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | (b) (4), (b) (6)           | Query 1: Reissued: Opened            | If Visit was Not done, please tick the Erroneous Visit button on the Date of Visit CRF. Any forms within the visit which were started in error should be marked Not Applicable at the form level. Or clarify. |
| Jan-11-2021<br>11:47:54<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | Binnur Yildirim<br>(b) (4) | Query 1: Answered                    | The second vaccination could not administer to the subject due to Covid-19 disease. So the second vaccination diary did not completed.  |
| Jan-11-2021<br>11:07:08<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY<br>(b) (4)       | Query 1: Opened                      | DMW6739235; Reactions Occur? are not expected to be Unknown or Not Applicable. Please review and update appropriately for all reactions or clarify  |
| Jan-08-2021<br>12:59:33<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br>Not Applicable | Initial Entry   |

5.b

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Jan-15-2021 13:30:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Injection Site Reaction::</b> Not Applicable<br><b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> Not Done       | Initial Entry |
| Jan-08-2021 12:59:33<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Injection Site Reaction::</b> Not Applicable<br><b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> Not Applicable | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:03

Form Status: Data Complete, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.b Injection Site Reaction:

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Jan-08-2021 12:59:33<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

5.b Were injection site reactions present on the last day the Subject Diary was completed?

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Jan-15-2021 13:30:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done       | Initial Entry |
| Jan-08-2021 12:59:33<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

5.c

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Jan-15-2021 13:30:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Injection Site Reaction::</b> Not Applicable<br><b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> Not Done       | Initial Entry |
| Jan-08-2021 12:59:33<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Injection Site Reaction::</b> Not Applicable<br><b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> Not Applicable | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

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

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:03

**Form Status:** Data Complete, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

**5.c Injection Site Reaction:**

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Jan-08-2021 12:59:33<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

**5.c Were injection site reactions present on the last day the Subject Diary was completed?**

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Jan-15-2021 13:30:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done       | Initial Entry |
| Jan-08-2021 12:59:33<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | 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, Frozen, Verified**Site No:** 1217**Site Name:** (1217) Kocaeli University Faculty of Medicine**Subject No:** 12171044**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Jan-08-2021 13:00:26<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                       | Reason        |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Jan-08-2021 13:00:26<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value  | Reason   |
|--|-----------------|---------------------------|--|--|
| Jan-08-2021 13:00:48<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted   | Close Auto Query   |
| Jan-08-2021 13:00:26<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate   | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Jan-08-2021 13:00:26<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Jan/8/2021 | Initial Entry  |

**5.a**

| Date   | Location        | User                | Value                                   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Jan-08-2021 13:00:48<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Sample ID: BN896M | Initial Entry |

**5.a Sample ID**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Jan-08-2021 13:00:48<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BN896M | Initial Entry |

**5.b**

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, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Jan-08-2021 13:01:01<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BN896N | Initial Entry |

**5.b Sample ID**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Jan-08-2021 13:01:01<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BN896N | Initial Entry |

**5.c**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Jan-08-2021 13:01:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BS2S8S | Initial Entry |

**5.c Sample ID**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Jan-08-2021 13:01:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BS2S8S | Initial Entry |

**5.d**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Jan-08-2021 13:01:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BS2S8T | Initial Entry |

**5.d Sample ID**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Jan-08-2021 13:01:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BS2S8T | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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*I. Date of Visit*

| Date   | Location        | User                | Value                    | Reason   |
|--|-----------------|---------------------|--------------------------|--|
| Nov-27-2020 20:17:45<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 5: Closed          | Response satisfies query   |
| Nov-26-2020 15:41:39<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 5: Answered        | Ill severe page updated  |
| Nov-25-2020 19:43:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 5: Opened          | Clin: As no data entered in ILL SEVERE, please mark with FORM LEVEL comment of Not Applicable.       |
| Nov-16-2020 20:11:58<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 4: Closed          | Response satisfies query   |
| Nov-16-2020 19:57:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 4: Answered        | the Imaging page was entered but there is no respiratory therapy yet.                                |
| Nov-16-2020 17:24:17<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 4: Reissued:Opened | Clin: Was any respiratory therapy or imaging performed?  |
| Nov-16-2020 16:43:02<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 4: Answered        | entered  |
| Nov-16-2020 16:33:57<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 4: Reissued:Opened | Clin: Please enter PULSE OX, RESP TX, IMAGING. Please make every effort to obtain these information. |
| Nov-16-2020 16:33:04<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 3: Closed          | Response satisfies query   |
| Nov-16-2020 15:59:04<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 4: Answered        | updated  |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

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

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**Site No:** 1217

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**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

|  |                 |                           |                    |  |
|--|-----------------|---------------------------|--------------------|--|
| Nov-16-2020 15:58:18<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 3: Answered  | updated  |
| Nov-16-2020 11:52:37<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 2: Closed    | Close Auto Query   |
| Nov-14-2020 23:33:25<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 4: Opened    | Clin: If subject was hospitalized, please enter on the CRF form any available information (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...). Please make every effort to obtain these information. |
| Nov-14-2020 23:31:15<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 3: Opened    | Clinical Query: Per CRF CRs Section 8.29, please complete HLTHCARE form.   |
| Nov-13-2020 02:27:48<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 2: Opened    | Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.  |
| Nov-12-2020 17:08:27<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted   | Close Auto Query   |
| Nov-12-2020 17:06:59<br>(UTC+03:00) Istanbul | 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.  |
| Nov-12-2020 17:06:59<br>(UTC+03:00) Istanbul | 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.   |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

|  |                 |                     |                                   |               |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Nov-12-2020 17:06:59<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/12/2020 | Initial Entry |
|--|-----------------|---------------------|-----------------------------------|---------------|

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

| Date   | Location        | User                    | Value                         | Reason        |
|--|-----------------|-------------------------|-------------------------------|---------------|
| Nov-12-2020 17:06:59<br>(UTC+03:00) Istanbul | 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 Nov/12/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Not Complete**Site No:** 1217**Site Name:** (1217) Kocaeli University Faculty of Medicine**Subject No:** 12171044**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Date of Assessment:**

| Date   | Location        | User                      | Value                             | Reason  |
|--|-----------------|---------------------------|-----------------------------------|---|
| Nov-17-2020 11:02:05<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)          | Query 1: Closed                   | Response satisfies query  |
| Nov-16-2020 11:52:37<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Answered                 | Initial Entry   |
| Nov-16-2020 11:52:37<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>Nov/12/2020 | Initial Entry   |
| Nov-14-2020 09:10:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Opened                   | DM: The response for Data item#1,2 and 3 are missing. Kindly review and update. |

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

| Date   | Location        | User                | Value                             | Reason              |
|--|-----------------|---------------------|-----------------------------------|---------------------|
| Nov-16-2020 12:08:55<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/10/2020 | Transcription Error |
| Nov-16-2020 11:52:37<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/11/2020 | Initial Entry       |

**3. Symptoms Ongoing?**

| Date   | Location        | User                      | Value  | Reason                                |
|--|-----------------|---------------------------|--|---------------------------------------|
| Feb-16-2021 17:50:08<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 2: Closed  | Response satisfies query              |
| Feb-16-2021 10:42:05<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 2: Answered  | data was updated.                     |
| Feb-16-2021 10:42:05<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>NO<br>Date of Last Symptom Resolved:<br>Feb/9/2021 | data was updated.                     |
| Feb-15-2021 14:10:02<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 2: Opened  | DM Query: Please confirm the symptoms |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

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

**Form Status:** Data Complete, Not Complete

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

|   |                 |                         |   |  |
|---|-----------------|-------------------------|---|--|
|   |                 | (b) (4), (b) (6)        |   | are still ongoing for this COVID Illness. If all symptoms for this illness are resolved; please update the Last Symptoms Resolved Date else clarify. |
| Jan-06-2021 15:19:12 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)        | <b>Data Entry:</b><br>YES   | Subject symptoms ongoing   |
| Dec-29-2020 21:10:06 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)        | Query 1: Closed   | Response satisfies query   |
| Dec-29-2020 13:57:36 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query (autoquery)  | Query 1: Answered   | end date was updated.  |
| Dec-29-2020 13:57:36 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b><br>NO<br>Date of Last Symptom Resolved:<br><br>Dec/15/2020 | end date was updated.  |
| Dec-28-2020 19:27:28 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)        | Query 1: Opened   | Clin: Please enter end date.   |
| Nov-23-2020 15:27:20 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b><br>YES   | Transcription Error  |
| Nov-19-2020 19:11:18 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b><br>NO<br>Date of Last Symptom Resolved:<br><br>Nov/16/2020 | New Information  |
| Nov-16-2020 11:52:37 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)        | <b>Data Entry:</b><br>YES   | Initial Entry  |

**4.a**

| Date                                      | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Nov-13-2020 14:57:44 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Symptoms:</b> FEVER<br><b>Symptom Present:</b> YES | Initial Entry |

**4.a Symptoms:**

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Not Complete**Site No:** 1217**Site Name:** (1217) Kocaeli University Faculty of Medicine**Subject No:** 12171044**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11

| Date   | Location        | User                | Value                       | Reason        |
|--|-----------------|---------------------|-----------------------------|---------------|
| Nov-13-2020 14:57:44<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>FEVER | Initial Entry |

**4.a Was symptom present?**

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Nov-13-2020 14:57:44<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

**4.b**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-13-2020 14:57:44<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptoms:</b> NEW OR INCREASE<br>D COUGH<br><b>Symptom Present:</b> NO | Initial Entry |

**4.b Symptoms:**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-13-2020 14:57:44<br>(UTC+03:00) Istanbul | 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        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-13-2020 14:57:44<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**4.c**

| Date   | Location        | User                | Value  | Reason          |
|--|-----------------|---------------------|--|-----------------|
| Nov-24-2020 11:33:15<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptoms:</b> NEW OR INCREASED S<br>HORTNESS OF BREATH<br><b>Symptom Present:</b> YES | New Information |
| Nov-13-2020 14:57:44<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b>   | Initial Entry   |

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Not Complete

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |                  |  |
|--|--|------------------|--|
|  |  | (b) (4), (b) (6) | <b>Symptom</b> NEW OR INCREASED S<br>s: HORTNESS OF BREATH<br><b>Symptom</b> NO<br><b>Present:</b> |
|--|--|------------------|--|

4.c Symptoms:

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-13-2020 14:57:44<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NEW OR INCREASED SHORTNESS<br>OF BREATH | Initial Entry |

4.c Was symptom present?

| Date   | Location        | User                | Value                     | Reason          |
|--|-----------------|---------------------|---------------------------|-----------------|
| Nov-24-2020 11:33:15<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | New Information |
| Nov-13-2020 14:57:44<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO  | Initial Entry   |

4.d

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-13-2020 14:57:44<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptoms:</b> CHILLS<br><b>Symptom Present:</b> NO | Initial Entry |

4.d Symptoms:

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Nov-13-2020 14:57:44<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>CHILLS | Initial Entry |

4.d Was symptom present?

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-13-2020 14:57:44<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

4.e

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Not Complete

Site No: 1217

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-13-2020 14:57:44<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptoms:</b> NEW OR INCREASED MUSCLE PAIN<br><b>Symptom P</b> YES<br><b>resent:</b> | Initial Entry |

4.e Symptoms:

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-13-2020 14:57:44<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NEW OR INCREASED MUSCLE PAI<br>N | Initial Entry |

4.e Was symptom present?

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Nov-13-2020 14:57:44<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

4.f

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-13-2020 14:57:44<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptoms:</b> NEW LOSS OF TASTE OR SMELL<br><b>Symptom Pr</b> YES<br><b>esent:</b> | Initial Entry |

4.f Symptoms:

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-13-2020 14:57:44<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(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        |
|--|-----------------|---------------------|---------------------------|---------------|
| Nov-13-2020 14:57:44<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

4.g

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-13-2020 14:57:44<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptoms:</b> NEW OR INCREASED SORE THROAT<br><b>Symptom P</b> NO<br><b>resent:</b> | Initial Entry |

4.g Symptoms:

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-13-2020 14:57:44<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NEW OR INCREASED SORE THRO<br>AT | Initial Entry |

4.g Was symptom present?

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-13-2020 14:57:44<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

4.h

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-13-2020 14:57:44<br>(UTC+03:00) Istanbul | 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        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Nov-13-2020 14:57:44<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>DIARRHEA | Initial Entry |

4.h Was symptom present?

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-13-2020 14:57:44<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

4.i

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

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Not Complete

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |                 |                     |   |               |
|--|-----------------|---------------------|---|---------------|
| Nov-13-2020 14:57:44<br>(UTC+03:00) Istanbul | 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        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Nov-13-2020 14:57:44<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>VOMITING | Initial Entry |

**4.i Was symptom present?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-13-2020 14:57:44<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**5.a**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-16-2020 11:54:26<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptoms - Other:</b> sweating | Initial Entry |

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

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Nov-16-2020 11:54:26<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>sweating | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** MICROBIOLOGY SPECIMEN - Audit Trail

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

**Form Status:**

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Date   | Location        | User                | Value        | Reason |
|--|-----------------|---------------------|--------------|--------|
| Nov-13-2020 11:30:12<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Form Created |        |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** MICROBIOLOGY SPECIMEN - Audit Trail

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

**Form Status:**

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Date   | Location        | User                          | Value        | Reason |
|--|-----------------|-------------------------------|--------------|--------|
| Nov-23-2020 15:29:56<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Created |        |

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Actual Date of Collection:**

| Date   | Location        | User                | Value                             | Reason              |
|--|-----------------|---------------------|-----------------------------------|---------------------|
| Nov-16-2020 12:09:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/10/2020 | Transcription Error |
| Nov-13-2020 11:30:12<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/11/2020 | Initial Entry       |

**2. Specimen Type:**

| Date   | Location        | User                | Value                                  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-13-2020 11:30:12<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>SWABBED MATERIAL | Initial Entry |

**3. Specimen Collection Location:**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Nov-13-2020 11:30:12<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NASOPHARYNX | Initial Entry |

**4. Assay Code and Description:**

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-13-2020 11:30:12<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SEVERE ACUTE RESP SYNDROME<br>CORONAVIRUS 2 | Initial Entry |

**5. Device Type:**

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Nov-13-2020 11:30:12<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SARS-COV-2 DIAGNOSTIC TEST | Initial Entry |

**6. Trade Name:**

| Date   | Location        | User                | Value           | Reason                   |
|--|-----------------|---------------------|-----------------|--------------------------|
| Nov-17-2020 13:26:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Closed | Response satisfies query |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |                 |                           |                             |   |
|--|-----------------|---------------------------|-----------------------------|---|
| Nov-16-2020 14:52:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 2: Closed             | Close Auto Query  |
| Nov-16-2020 14:47:08<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 2: Opened             | Trade Name is Other, however Trade Name Other, Specify is not completed. Please update. |
| Nov-16-2020 14:47:08<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Answered           | Initial Entry   |
| Nov-16-2020 14:47:08<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>OTHER | Initial Entry   |
| Nov-14-2020 09:05:57<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Opened             | DM: The response for "Trade Name" is missing. Kindly review and update.                 |

7. Test Result:

| Date   | Location        | User                | Value                          | Reason   |
|--|-----------------|---------------------|--------------------------------|--|
| Nov-16-2020 17:23:09<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Closed                | Response satisfies query   |
| Nov-16-2020 17:11:13<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Answered              | EOT page was entered   |
| Nov-16-2020 16:51:44<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Opened                | Clin: As subject is symptomatic and has a positive COVID-19 local lab result, please complete EOT CRF with Status of "No longer meets an eligibility criteria" and Specify Status of "Exclusion criterion 5." VAX2 is not given but FUP will be completed. |
| Nov-13-2020 11:30:12<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>POSITIVE | Initial Entry  |

9. Trade Name Other, Specify:

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

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

|  |                 |                            |                           |  |
|--|-----------------|----------------------------|---------------------------|--|
| Nov-23-2020<br>08:31:24<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)           | Query 1: Closed           | Response satisfies query   |
| Nov-19-2020<br>18:21:19<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | Query 1: Answered         | Test was performed at the site. Lab name is Kocaeli Universitesi Arastirma ve Uygulama Hsstanesi, Tibbi Mikrobiyoloji Laboratuvari. The lab has Turkey's Ministry of Health License. License no:438/03                     |
| Nov-19-2020<br>08:59:52<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | Query 1: Reissued: Opened | DM: Please consider to update 'Trade Name Other, Specify' to indicate if it is 'CLIA-certified lab' or 'ISO 15189 accredited lab' as per section 8.31.7 of completion guidelines. Please verify and update as appropriate. |
| Nov-18-2020<br>15:29:02<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | Query 1: Answered         | Data is correct. This PCR test has been already approved and sent by Turkish Ministry of Health.   |
| Nov-18-2020<br>09:39:03<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)           | Query 1: Reissued: Opened | DM : This Test is not indicated on the FDA-cleared (including  |

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

|  |   |                         |   |   |
|--|---|-------------------------|---|---|
|  |   |                         |   | Emergency Use Authorization) diagnostic list and is not indicated as 'CLIA-certified lab' or 'ISO 15189 accredited lab' Please review and update. Else, clarify.  |
| Nov-17-2020<br>19:31:01<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)     | Query 1: Answered                                   | Original value is correct   |
| Nov-17-2020<br>15:37:12<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFE SDQ PROD<br>(b) (4) | Query 1: Opened                                     | coronex-covid 19 rt-qpcr test is not indicated on the FDA-cleared (including Emergency Use Authorization) diagnostic list and is not indicated as 'CLIA-certified lab' or 'ISO 15189 accredited lab' . Please verify and update as appropriate. Otherwise, please provide clarification.<br>(b) (4) |
| Nov-16-2020<br>16:04:52<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)     | <b>Data Entry:</b><br>CORONEX-COVID 19 RT-qPCR Test | Transcription Error   |
| Nov-16-2020<br>14:52:34<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)     | <b>Data Entry:</b><br>CORONEX-COVID 19 RT-qPCR Test | Initial Entry   |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Actual Date of Collection:**

| Date   | Location        | User                       | Value                             | Reason        |
|--|-----------------|----------------------------|-----------------------------------|---------------|
| Nov-23-2020 15:29:56<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Nov/16/2020 | Initial Entry |

**2. Specimen Type:**

| Date   | Location        | User                       | Value                                  | Reason        |
|--|-----------------|----------------------------|--|---------------|
| Nov-23-2020 15:29:56<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>SWABBED MATERIAL | Initial Entry |

**3. Specimen Collection Location:**

| Date   | Location        | User                       | Value                             | Reason        |
|--|-----------------|----------------------------|-----------------------------------|---------------|
| Nov-23-2020 15:29:56<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>NASOPHARYNX | Initial Entry |

**4. Assay Code and Description:**

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-23-2020 15:29:56<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SEVERE ACUTE RESP SYNDROME<br>CORONAVIRUS 2 | Initial Entry |

**5. Device Type:**

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Nov-23-2020 15:29:56<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SARS-COV-2 DIAGNOSTIC TEST | Initial Entry |

**6. Trade Name:**

| Date   | Location        | User                         | Value             | Reason                   |
|--|-----------------|------------------------------|-------------------|--------------------------|
| Dec-02-2020 19:54:06<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 3: Closed   | Response satisfies query |
| Nov-30-2020 16:47:01<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)          | Query 3: Answered | data was change          |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen, Verified**Site No:** 1217**Site Name:** (1217) Kocaeli University Faculty of Medicine**Subject No:** 12171044**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11

|  |                 |                              |                          |  |
|--|-----------------|------------------------------|--------------------------|--|
| Nov-30-2020 04:29:55<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 4: Closed          | Response satisfies query   |
| Nov-30-2020 04:29:25<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 2: Closed          | Response satisfies query   |
| Nov-30-2020 04:29:11<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 3: Reissued:Opened | Medical monitor: Since any of the suggestions was entered please enter "NALT Unknown" instead of "CORONEX-COVID 19 RT-qPCR Test"   |
| Nov-25-2020 11:45:19<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)          | Query 4: Answered        | The trade name already known, 'CORONEX-COVID19 RT-qPCR TEST'. However the local lab has no CLIA-certificate.ISO 15189 accreditation. There is only the lab has only Turkey's Ministry of Health License. License no:438/03 |
| Nov-25-2020 11:37:42<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)          | Query 3: Answered        | There is no ISO 15189 accreditation.The lab has only Turkey's Ministry of Health License. License no:438/03  |
| Nov-25-2020 11:36:58<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)          | Query 2: Answered        | There is no CLIA-certified. The lab has only Turkey's Ministry of Health License. License no:438/03  |
| Nov-25-2020 00:37:17<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b)<br>(6)          | Query 4: Opened          | Clin: For guidance how to complete this CRF form, please refer to the CRF COMPLETION REQUIREMENTS FOR INFORM section 8.31.7. page 138  |
| Nov-25-2020 00:37:17<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b)<br>(6)          | Query 3: Opened          | Clin: If manufacturer/test kit name is not available,  |



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

|  |                 |                              |                    |  |
|--|-----------------|------------------------------|--------------------|--|
|  |                 |                              |                    | please indicate whether the test was performed by a laboratory accredited by the ISO 15189 standard by including the text 'ISO 15189 accredited lab' (ie SARS-CoV-2 test ISO 15189 accredited lab)   |
| Nov-25-2020 00:37:17<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)             | Query 2: Opened    | Clin: If manufacturer/test kit name is not available, please indicate whether the test was conducted in a CLIA- certified laboratory by including the text 'CLIA-certified lab' (ie SARS-CoV-2 test CLIA-certified lab)                                  |
| Nov-24-2020 21:08:46<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 4: Candidate | Clin: For guidance how to complete this CRF form, please refer to the CRF COMPLETION REQUIREMENTS FOR INFORM section 8.31.7. page 138  |
| Nov-24-2020 21:07:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 3: Candidate | Clin: If manufacturer/test kit name is not available, please indicate whether the test was performed by a laboratory accredited by the ISO 15189 standard by including the text 'ISO 15189 accredited lab' (ie SARS-CoV-2 test ISO 15189 accredited lab) |
| Nov-24-2020 21:07:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 2: Candidate | Clin: If manufacturer/test kit name is not available, please indicate whether the test was conducted in a CLIA- certified laboratory by including  |

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |                 |                            |                             |   |
|--|-----------------|----------------------------|-----------------------------|---|
|  |                 |                            |                             | the text 'CLIA-certified lab' (ie SARS-CoV-2 test CLIA-certified lab)                   |
| Nov-23-2020 15:30:52<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)  | Query 1: Closed             | Close Auto Query  |
| Nov-23-2020 15:29:56<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)  | Query 1: Opened             | Trade Name is Other, however Trade Name Other, Specify is not completed. Please update. |
| Nov-23-2020 15:29:56<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>OTHER | Initial Entry   |

7. Test Result:

| Date   | Location        | User                       | Value                          | Reason        |
|--|-----------------|----------------------------|--------------------------------|---------------|
| Nov-23-2020 15:29:56<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>POSITIVE | Initial Entry |

9. Trade Name Other, Specify:

| Date   | Location        | User                         | Value                               | Reason  |
|--|-----------------|------------------------------|-------------------------------------|---|
| Nov-30-2020 16:46:13<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)          | <b>Data Entry:</b><br>NALT Unkn own | Changed Information   |
| Nov-30-2020 04:29:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 2: Closed                     | Response satisfies query  |
| Nov-26-2020 09:07:26<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)             | Query 1: Closed                     | Response satisfies query  |
| Nov-25-2020 11:50:02<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)          | Query 2: Answered                   | The trade name already known, 'CORONEX-COVID19 RT-qPCR TEST'. However the local lab has no CLIA-certificate, ISO 15189 accreditation. There is only the lab has only Turkey's |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen, Verified**Site No:** 1217**Site Name:** (1217) Kocaeli University Faculty of Medicine**Subject No:** 12171044**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11

|  |                 |                              |                          |  |
|--|-----------------|------------------------------|--------------------------|--|
|  |                 |                              |                          | Ministry of Health License. License no:438/03  |
| Nov-25-2020<br>11:49:52<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)          | Query 1: Answered        | The trade name already known, 'CORONEX-COVID19 RT-qPCR TEST'. However the local lab has no CLIA-certificate,ISO 15189 accreditation. There is only the lab has only Turkey's Ministry of Health License. License no:438/03   |
| Nov-25-2020<br>00:37:17<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)             | Query 2: Opened          | Clin: If manufacturer/test kit name is not available, please indicate whether the test was conducted in a CLIA-certified laboratory by including the text 'CLIA-certified lab' (ie SARS-CoV-2 test CLIA-certified lab)       |
| Nov-25-2020<br>00:31:04<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)             | Query 1: Reissued:Opened | If the Trade Name is not known whether the test was performed in a CLIA-certified laboratory or in a laboratory accredited by the ISO 15189 standard by a national or regional accredited body, please enter "NALT Unknown". |
| Nov-24-2020<br>21:06:49<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 2: Candidate       | Clin: If manufacturer/test kit name is not available, please indicate whether the test was conducted in a CLIA-certified laboratory by including the text  |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

|  |   |                            |   |   |
|--|---|----------------------------|---|---|
|  |   |                            |   | 'CLIA-certified lab'<br>(ie SARS-CoV-2 test<br>CLIA-certified lab)  |
| Nov-24-2020<br>15:40:47<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)        | Query 1: An<br>swered                                       | Test was performed<br>at the site.Lab name<br>is Kocaeli<br>Universitesi<br>Arastirma ve<br>Uygulama Hsstanesi,<br>Tibbi Mikrobiyoloji<br>Laboratuvari. The lab<br>has Turkey's Ministry<br>of Health License.<br>License no:438/03   |
| Nov-24-2020<br>15:36:34<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFE SDQ PROD<br>(b) (4)    | Query 1: Op<br>ened   | coronex covid 19 rt<br>qpcr test is not<br>indicated on the FDA<br>cleared (including<br>Emergency Use<br>Authorization)<br>diagnostic list and is<br>not indicated as<br>CLIA certified lab or<br>ISO 15189 accredited<br>lab . Please verify<br>and update as<br>appropriate.<br>Otherwise, please<br>provide clarification.<br>(b) (4) |
| Nov-23-2020<br>15:30:52<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>CORONEX-<br>COVID 19 R<br>T-qPCR Test | Initial Entry   |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1217**Site Name:** (1217) Kocaeli University Faculty of Medicine**Subject No:** 12171044**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Data Origin**

| Date   | Location        | User                    | Value                                | Reason        |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Nov-18-2020 20:57:24<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE           | Initial Entry |
| Nov-18-2020 20:56:31<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | <b>Data Entry:</b>                   | Initial Entry |
| Nov-17-2020 15:08:35<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | <b>Data Entry:</b><br>Not Done       | Initial Entry |
| Nov-16-2020 11:58:01<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | <b>Data Entry:</b><br>Not Applicable | Initial Entry |
| Nov-12-2020 17:09:03<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | <b>Data Entry:</b><br>Not Done       | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                                 | Reason        |
|--|-----------------|-------------------------|---------------------------------------|---------------|
| Nov-18-2020 20:57:24<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB_SELF | Initial Entry |
| Nov-18-2020 20:56:31<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | <b>Data Entry:</b>                    | Initial Entry |
| Nov-17-2020 15:08:35<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | <b>Data Entry:</b><br>Not Done        | Initial Entry |
| Nov-16-2020 11:58:01<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | <b>Data Entry:</b><br>Not Applicable  | Initial Entry |
| Nov-12-2020 17:09:03<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | <b>Data Entry:</b><br>Not Done        | Initial Entry |

**3. Sample Collected?**

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

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1217**Site Name:** (1217) Kocaeli University Faculty of Medicine**Subject No:** 12171044**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11

|  |   |                            |                                |  |
|--|---|----------------------------|--------------------------------|--|
| Nov-19-2020<br>00:02:27<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY<br>(b) (4)       | Query 3: Closed                | Auto closed by Validation Check:<br>VC_BEETRK001_07  |
| Nov-18-2020<br>20:57:24<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | auto query<br>(autoquery)  | Query 3: Answered              | Initial Entry  |
| Nov-18-2020<br>20:57:24<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br>NO       | Initial Entry  |
| Nov-18-2020<br>20:56:31<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)        | <b>Data Entry:</b>             | Initial Entry  |
| Nov-18-2020<br>14:19:12<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY<br>(b) (4)       | Query 3: Opened                | DMW5402079;Sample Collected is not expected to be Not Done. Please review and update appropriately or clarify  |
| Nov-17-2020<br>23:48:02<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY<br>(b) (4)       | Query 2: Closed                | Auto closed by Validation Check:<br>VC_BEETRK001_05  |
| Nov-17-2020<br>15:40:39<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | Binnur Yildirim<br>(b) (4) | Query 2: Answered              | patient did not use "self" nasal swab. the nasal swab was collected by sub investigator in the hospital and sent the central lab on 12 nov2020. so the page SWAB PFE page updated for this test. even so should I enter this informations to SELF SWAB page? |
| Nov-17-2020<br>15:08:35<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br>Not Done | Initial Entry  |
| Nov-17-2020<br>12:32:16                            | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY<br>(b) (4)       | Query 2: Opened                | DMW5386800;Sample Collected is not   |

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1217**Site Name:** (1217) Kocaeli University Faculty of Medicine**Subject No:** 12171044**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11

|  |   |                      |                                      |   |
|--|---|----------------------|--------------------------------------|---|
| (UTC+03:00)<br>Istanbul                            |   |                      |                                      | expected to be Unknown or Not Applicable. Please review and update appropriately or clarify                   |
| Nov-16-2020<br>17:22:13<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY<br>(b) (4) | Query 1: Closed                      | Auto closed by Validation Check: VC_BEETRK001_07  |
| Nov-16-2020<br>11:58:44<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)  | Query 1: Answered                    | self nasal swab is not expected so not done   |
| Nov-16-2020<br>11:58:01<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)  | <b>Data Entry:</b><br>Not Applicable | Initial Entry   |
| Nov-13-2020<br>14:30:36<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY<br>(b) (4) | Query 1: Opened                      | DMW5369590;Sample Collected is not expected to be Not Done. Please review and update appropriately or clarify |
| Nov-12-2020<br>17:09:03<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)  | <b>Data Entry:</b><br>Not Done       | Initial Entry   |

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

| Date   | Location        | User                      | Value  | Reason   |
|--|-----------------|---------------------------|--|--|
| Nov-18-2020 20:58:48<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Closed  | Close Auto Query   |
| Nov-18-2020 20:58:48<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>the nasal swab was collected in the hospital.patient has not used SELF SWAB kit. | Transcription Error  |
| Nov-18-2020 20:57:24<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Opened  | Entered text has either a carriage return (line break) or extra spaces at the end of the text or between words. Please correct by removing all data in the field and re-enter without adding |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

**Site No:** 1217

**Subject No:** 12171044

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

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

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

|  |                 |                     |  |  |
|--|-----------------|---------------------|--|--|
|  |                 |                     |  | extra spaces or using enter or tab keys. |
| Nov-18-2020 20:57:24<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>the nasal swab was collected in the hospital. patient has not used SELF SWAB kit | Initial Entry                            |
| Nov-18-2020 20:56:31<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b>   | Initial Entry                            |
| Nov-17-2020 15:08:35<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done   | Initial Entry                            |
| Nov-16-2020 11:58:01<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable   | Initial Entry                            |
| Nov-12-2020 17:09:03<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done   | Initial Entry                            |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)



**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020**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:** 1217**Site Name:** (1217) Kocaeli University Faculty of Medicine**Subject No:** 12171044**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Nov-12-2020 17:08:27<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Nov-12-2020 17:08:27<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value   | Reason   |
|--|-----------------|---------------------------|---|--|
| Nov-12-2020 17:08:50<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted  | Close Auto Query   |
| Nov-12-2020 17:08:27<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate  | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Nov-12-2020 17:08:27<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Nov/12/2020 | Initial Entry  |

**5.a**

| Date   | Location        | User                | Value  | Reason              |
|--|-----------------|---------------------|--|---------------------|
| Nov-12-2020 17:38:56<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BPZ9GC | Transcription Error |
| Nov-12-2020 17:08:50<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BPZ9GB | Initial Entry       |

**5.a Sample ID**

| Date                 | Location        | User             | Value              | Reason              |
|----------------------|-----------------|------------------|--------------------|---------------------|
| Nov-12-2020 17:38:56 | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b> | Transcription Error |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

**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:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

|  |                 |                     |                              |               |
|--|-----------------|---------------------|------------------------------|---------------|
| (UTC+03:00) Istanbul                         |                 | (b) (4),<br>(b) (6) | BPZ9GC                       |               |
| Nov-12-2020 17:08:50<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BPZ9GB | Initial Entry |

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1217**Site Name:** (1217) Kocaeli University Faculty of Medicine**Subject No:** 12171044**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**I.a**

| Date   | Location        | User                       | Value   | Reason              |
|--|-----------------|----------------------------|---|---------------------|
| Nov-23-2020 15:38:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Type of Practitioner: SPECIALIST<br>Occurrence of Visits or Contacts: YES<br>Number of Visits or Contacts:<br>2 | Changed Information |
| Nov-16-2020 12:01:07<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br>Type of Practitioner: SPECIALIST<br>Occurrence of Visits or Contacts: YES<br>Number of Visits or Contacts:<br>1 | Initial Entry       |

**I.a Physician or Healthcare Professional:**

| Date   | Location        | User                | Value                            | Reason        |
|--|-----------------|---------------------|----------------------------------|---------------|
| Nov-16-2020 12:01:07<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>SPECIALIST | Initial Entry |

**I.a Occurrence of Visits or Contacts:**

| Date   | Location        | User                       | Value   | Reason              |
|--|-----------------|----------------------------|---|---------------------|
| Nov-23-2020 15:38:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>YES<br>Number of Visits or Contacts:<br>2 | Changed Information |
| Nov-16-2020 12:01:07<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br>YES<br>Number of Visits or Contacts:<br>1 | Initial Entry       |

**I.b**

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-16-2020 12:01:07<br>(UTC+03:00) Istanbul | 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 |

**1.b Physician or Healthcare Professional:**

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-16-2020 12:01:07<br>(UTC+03:00) Istanbul | 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        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-16-2020 12:01:07<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**1.c**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-16-2020 12:01:07<br>(UTC+03:00) Istanbul | 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> NO | Initial Entry |

**1.c Physician or Healthcare Professional:**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-16-2020 12:01:07<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>PRIMARY CARE PHYSICIAN | Initial Entry |

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

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-16-2020 12:01:07<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**1.d**

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-16-2020 12:01:07<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(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        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Nov-16-2020 12:01:07<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>URGENT CARE | Initial Entry |

*1.d Occurrence of Visits or Contacts:*

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-16-2020 12:01:07<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

*1.e*

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-16-2020 12:01:07<br>(UTC+03:00) Istanbul | 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 |

*1.e Physician or Healthcare Professional:*

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-16-2020 12:01:07<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>TELEPHONE CONSULTATION | Initial Entry |

*1.e Occurrence of Visits or Contacts:*

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-16-2020 12:01:07<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

*1.f*

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-16-2020 12:01:07<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Type of Practitioner:</b> OTHE<br>R<br><b>Occurrence of Visits or Cont acts:</b> NO | Initial Entry |

*1.f Physician or Healthcare Professional:*

| Date   | Location        | User                | Value                       | Reason        |
|--|-----------------|---------------------|-----------------------------|---------------|
| Nov-16-2020 12:01:07<br>(UTC+03:00) Istanbul | 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        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-16-2020 12:01:07<br>(UTC+03:00) Istanbul | 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        |
|--|-----------------|---------------------|--|---------------|
| Nov-16-2020 12:01:07<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES<br>Has the subject been in intensive care due to potential COVID-19 illness?<br><br>NO | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** HOSPITALIZATION DETAILS - Audit Trail

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

**Form Status:**

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Date   | Location        | User                | Value        | Reason |
|--|-----------------|---------------------|--------------|--------|
| Nov-16-2020 12:01:42<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Form Created |        |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** HOSPITALIZATION DETAILS - Audit Trail

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

**Form Status:**

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Date   | Location        | User                          | Value        | Reason |
|--|-----------------|-------------------------------|--------------|--------|
| Nov-23-2020 15:40:59<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Created |        |



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Hospitalization Category:**

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Nov-16-2020 12:01:42<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>HOSPITALIZATION STATUS | Initial Entry |

**2. Hospitalization Term:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Nov-16-2020 12:01:42<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>HOSPITAL | Initial Entry |

**3. Admission Date:**

| Date   | Location        | User                | Value                             | Reason              |
|--|-----------------|---------------------|-----------------------------------|---------------------|
| Nov-16-2020 12:10:19<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/11/2020 | Transcription Error |
| Nov-16-2020 12:01:42<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/12/2020 | Initial Entry       |

**4. Ongoing?**

| Date   | Location        | User                          | Value  | Reason          |
|--|-----------------|-------------------------------|--|-----------------|
| Nov-23-2020 15:40:18<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>NO<br>Discharge Date:<br>Nov/16/2020 | New Information |
| Nov-16-2020 12:01:42<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b><br>YES                                  | Initial Entry   |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Hospitalization Category:**

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Nov-23-2020 15:40:59<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>HOSPITALIZATION STATUS | Initial Entry |

**2. Hospitalization Term:**

| Date   | Location        | User                          | Value                          | Reason        |
|--|-----------------|-------------------------------|--------------------------------|---------------|
| Nov-23-2020 15:40:59<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>HOSPITAL | Initial Entry |

**3. Admission Date:**

| Date   | Location        | User                          | Value                             | Reason        |
|--|-----------------|-------------------------------|-----------------------------------|---------------|
| Nov-23-2020 15:40:59<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Nov/20/2020 | Initial Entry |

**4. Ongoing?**

| Date   | Location        | User                          | Value  | Reason          |
|--|-----------------|-------------------------------|--|-----------------|
| Dec-02-2020 14:03:06<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b><br>NO<br>Discharge Date:<br>Nov/29/2020 | New Information |
| Nov-23-2020 15:40:59<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>YES                                  | Initial Entry   |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** RESPIRATORY TREATMENT - Audit Trail

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

**Form Status:**

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Date   | Location        | User                | Value        | Reason |
|--|-----------------|---------------------|--------------|--------|
| Nov-13-2020 11:32:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Form Created |        |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** RESPIRATORY TREATMENT - Audit Trail

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

**Form Status:**

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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

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| Date   | Location        | User                          | Value        | Reason                 |
|--|-----------------|-------------------------------|--------------|------------------------|
| Dec-09-2020 09:34:49<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | Form Deleted | Transcription<br>Error |
| Dec-07-2020 10:48:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Created |                        |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** RESPIRATORY TREATMENT - Audit Trail

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

**Form Status:**

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Date   | Location        | User                          | Value        | Reason |
|--|-----------------|-------------------------------|--------------|--------|
| Dec-07-2020 10:49:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Created |        |

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. What is the treatment Identifier?**

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Nov-13-2020 11:32:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>1 | Initial Entry |

**2. Concomitant Non-drug Treatment Pre-specified:**

| Date   | Location        | User                    | Value                     | Reason              |
|--|-----------------|-------------------------|---------------------------|---------------------|
| Nov-23-2020 15:48:56<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>YES | Initial Entry       |
| Nov-16-2020 16:27:14<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b>        | Transcription Error |
| Nov-13-2020 11:32:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>YES | Initial Entry       |

**3. Treatment:**

| Date   | Location        | User                       | Value  | Reason              |
|--|-----------------|----------------------------|--|---------------------|
| Nov-23-2020 15:48:56<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>NON-INVASIVE POSITIVE PRESSURE VENTILATION | Initial Entry       |
| Nov-23-2020 15:43:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b>   | Initial Entry       |
| Nov-16-2020 16:35:12<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br>Not Applicable                             | Initial Entry       |
| Nov-16-2020 16:27:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b>   | Transcription Error |
| Nov-13-2020 11:32:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br>NON-INVASIVE POSITIVE PRESSURE VENTILATION | Initial Entry       |

**4. Treatment:**

| Date   | Location        | User                    | Value  | Reason              |
|--|-----------------|-------------------------|--|---------------------|
| Nov-23-2020 15:48:56<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NON-INVASIVE POSITIVE PRESSURE VENTILATION | Initial Entry       |
| Nov-16-2020 16:27:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b>   | Transcription Error |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 Form: RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |                 |                         |  |               |
|--|-----------------|-------------------------|--|---------------|
| Nov-13-2020 11:32:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NON-INVASIVE POSITIVE PRESSU<br>RE VENTILATION | Initial Entry |
|--|-----------------|-------------------------|--|---------------|

5. Start Date:

| Date   | Location        | User                          | Value                                | Reason              |
|--|-----------------|-------------------------------|--------------------------------------|---------------------|
| Nov-23-2020 15:48:56<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Nov/20/2020    | Initial Entry       |
| Nov-23-2020 15:43:46<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b>                   | Initial Entry       |
| Nov-16-2020 16:35:27<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b><br>Not Applicable | Initial Entry       |
| Nov-16-2020 16:27:14<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b>                   | Transcription Error |
| Nov-13-2020 11:32:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b><br>Nov/12/2020    | Initial Entry       |

6. Ongoing?

| Date   | Location        | User                          | Value  | Reason              |
|--|-----------------|-------------------------------|--|---------------------|
| Dec-09-2020 09:38:04<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b><br>NO<br>End Date:<br><br>Nov/21/2020 | New Information     |
| Nov-23-2020 15:48:56<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>YES                                | Initial Entry       |
| Nov-23-2020 15:44:18<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b>                                       | Initial Entry       |
| Nov-16-2020 16:35:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b><br>Not Applicable                     | Initial Entry       |
| Nov-16-2020 16:27:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b>                                       | Transcription Error |
| Nov-13-2020 11:32:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b><br>YES                                | Initial Entry       |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 Form: RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Deleted, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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

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1. What is the treatment Identifier?

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Dec-07-2020 10:48:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>2 | Initial Entry |

2. Concomitant Non-drug Treatment Pre-specified:

| Date   | Location        | User                    | Value                     | Reason        |
|--|-----------------|-------------------------|---------------------------|---------------|
| Dec-07-2020 10:48:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>YES | Initial Entry |

3. Treatment:

| Date   | Location        | User                          | Value  | Reason        |
|--|-----------------|-------------------------------|--|---------------|
| Dec-07-2020 10:48:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <u>Data Entry:</u><br>HIGH FLOW OXYGEN THERAPY | Initial Entry |

4. Treatment:

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Dec-07-2020 10:48:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>HIGH FLOW OXYGEN THERAPY | Initial Entry |

5. Start Date:

| Date   | Location        | User                          | Value                             | Reason        |
|--|-----------------|-------------------------------|-----------------------------------|---------------|
| Dec-07-2020 10:48:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <u>Data Entry:</u><br>Nov/20/2020 | Initial Entry |

6. Ongoing?

| Date   | Location        | User                          | Value  | Reason        |
|--|-----------------|-------------------------------|--|---------------|
| Dec-07-2020 10:48:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <u>Data Entry:</u><br>NO<br>End Date:<br>Nov/21/2020 | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. What is the treatment Identifier?**

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Dec-07-2020 10:49:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>3 | Initial Entry |

**2. Concomitant Non-drug Treatment Pre-specified:**

| Date   | Location        | User                    | Value                     | Reason        |
|--|-----------------|-------------------------|---------------------------|---------------|
| Dec-07-2020 10:49:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>YES | Initial Entry |

**3. Treatment:**

| Date   | Location        | User                          | Value  | Reason        |
|--|-----------------|-------------------------------|--|---------------|
| Dec-07-2020 10:49:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>HIGH FLOW OXYGEN THERAPY | Initial Entry |

**4. Treatment:**

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Dec-07-2020 10:49:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>HIGH FLOW OXYGEN THERAPY | Initial Entry |

**5. Start Date:**

| Date   | Location        | User                          | Value                             | Reason        |
|--|-----------------|-------------------------------|-----------------------------------|---------------|
| Dec-07-2020 10:49:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Nov/22/2020 | Initial Entry |

**6. Ongoing?**

| Date   | Location        | User                          | Value  | Reason        |
|--|-----------------|-------------------------------|--|---------------|
| Dec-07-2020 10:49:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>NO<br>End Date:<br>Nov/28/2020 | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Category of Clinical Event:**

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Nov-16-2020 12:05:30<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>POTENTIAL COVID-19 ILLNESS | Initial Entry |
| Nov-16-2020 12:02:26<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | <b>Data Entry:</b>                               | Initial Entry |
| Nov-13-2020 11:32:50<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | <b>Data Entry:</b><br>Not Done                   | Initial Entry |

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

| Date   | Location        | User                      | Value   | Reason  |
|--|-----------------|---------------------------|---|---|
| Nov-16-2020 16:58:44<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Closed   | Response satisfies query  |
| Nov-16-2020 16:56:35<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Answered   | Transcription Error   |
| Nov-16-2020 16:56:35<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>YES<br><i>Respiratory Illness Diagnosis:</i><br><br>Covid-19<br><br>Date of Diagnosis:<br><br>Nov/10/2020 | Transcription Error   |
| Nov-16-2020 16:49:45<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Reissued:Opened  | Clin: Diagnosis should be updated to "COVID-19".  |
| Nov-16-2020 16:44:50<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Answered   | local test was done on 10 nov 2020.   |
| Nov-16-2020 16:30:04<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Reissued:Opened  | Clin: Diagnosis of COVID-19 should be entered as subject is symptomatic and had a positive local test |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** ILLNESS DETAILS - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:52**Form Status:** Data Complete, Frozen, Verified**Site No:** 1217**Site Name:** (1217) Kocaeli University Faculty of Medicine**Subject No:** 12171044**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11

|  |                 |                           |  |   |
|--|-----------------|---------------------------|--|---|
|  |                 |                           |  | collected on<br>11Nov2020.  |
| Nov-16-2020 16:26:35<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 2: Closed  | Close Auto Query  |
| Nov-16-2020 16:26:35<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>YES<br><i>Respiratory Illness Diagnosis:</i><br><br>there is no Respiratory Illness diagnosis<br><br>Date of Diagnosis:<br><br>Nov/10/2020 | New Information   |
| Nov-16-2020 16:13:05<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>YES<br>Date of Diagnosis:<br><br>Nov/10/2020   | Transcription Error   |
| Nov-16-2020 12:05:30<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 2: Opened  | Yes is selected,<br>however, either the<br>diagnosis details or<br>date of diagnosis is<br>missing. Please<br>correct.                          |
| Nov-16-2020 12:05:30<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Answered  | Initial Entry   |
| Nov-16-2020 12:05:30<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>YES<br>Date of Diagnosis:<br><br>Nov/11/2020   | Initial Entry   |
| Nov-16-2020 12:02:26<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b>   | Initial Entry   |
| Nov-14-2020 02:39:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Opened  | Clin: As subject is<br>symptomatic and had<br>positive local test<br>collected on<br>11Nov2020, diagnosis<br>of COVID-19 should<br>be recorded. |
| Nov-13-2020 11:32:50<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>Not Done   | Initial Entry   |

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

3. Toxicity Grade:

| Date   | Location                                  | User                       | Value                       | Reason   |
|--|---|----------------------------|-----------------------------|--|
| Nov-23-2020<br>15:51:39<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | Binnur Yildirim<br>(b) (4) | <u>Data Entry</u><br>:<br>2 | Changed Information  |
| Nov-16-2020<br>17:23:30<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY<br>(b) (4)       | Query 2: Cl<br>osed         | Auto closed by<br>Validation Check:<br>VC_CEIDT008_03  |
| Nov-16-2020<br>16:28:38<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | (b) (4), (b)<br>(6)        | Query 1: Cl<br>osed         | Response satisfies<br>query  |
| Nov-16-2020<br>12:05:30<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | auto query<br>(autoquery)  | Query 2: A<br>nswered       | Initial Entry  |
| Nov-16-2020<br>12:05:30<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | auto query<br>(autoquery)  | Query 1: A<br>nswered       | Initial Entry  |
| Nov-16-2020<br>12:05:30<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)        | <u>Data Entry</u><br>:<br>1 | Initial Entry  |
| Nov-16-2020<br>12:02:26<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)        | <u>Data Entry</u><br>:      | Initial Entry  |
| Nov-14-2020<br>09:16:44<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY<br>(b) (4)       | Query 2: O<br>pened         | DMW5375552;Toxicity<br>Grade is not expected to<br>be Not Done or Not<br>Applicable or<br>Unknown. Please<br>review and update<br>appropriately or clarify |
| Nov-14-2020<br>02:40:06<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | (b) (4), (b)<br>(6)        | Query 1: O<br>pened         | Clinical Query: Per<br>CRF CRs Section<br>8.33.5, please enter<br>worst toxicity grade (1<br>to 5) as it relates to<br>reported symptom(s) on              |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** ILLNESS DETAILS - eCRF Audit Trail History

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

|  |                 |                     |                                    | SOD CRF.      |
|--|-----------------|---------------------|------------------------------------|---------------|
| Nov-13-2020<br>11:32:50<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry</b><br>:<br>Not Done | Initial Entry |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** ILLNESS DETAILS - SEVERE - Audit Trail

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

**Form Status:**

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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

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| Date   | Location        | User                | Value        | Reason                         |
|--|-----------------|---------------------|--------------|--------------------------------|
| Nov-24-2020 11:20:13<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Form Deleted | data was entered<br>by mistake |
| Nov-16-2020 16:45:48<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Form Created |                                |

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Deleted, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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

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**1. Category of Clinical Event:**

| Date   | Location        | User                    | Value   | Reason              |
|--|-----------------|-------------------------|---|---------------------|
| Nov-26-2020 15:40:47<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>Not Applicable          | Initial Entry       |
| Nov-24-2020 11:19:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u>                            | Transcription Error |
| Nov-23-2020 16:02:01<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>SEVERE COVID-19 ILLNESS | Initial Entry       |
| Nov-23-2020 15:53:57<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u>                            | Initial Entry       |
| Nov-16-2020 16:47:25<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>Not Applicable          | Initial Entry       |
| Nov-16-2020 16:47:03<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u>                            | Transcription Error |
| Nov-16-2020 16:45:48<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>SEVERE COVID-19 ILLNESS | Initial Entry       |
| Nov-16-2020 16:45:12<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | <u>Data Entry:</u>                            | Initial Entry       |
| Nov-16-2020 16:29:33<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | <u>Data Entry:</u><br>Not Applicable          | Initial Entry       |
| Nov-16-2020 12:05:49<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | <u>Data Entry:</u>                            | Initial Entry       |
| Nov-13-2020 11:33:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | <u>Data Entry:</u><br>Not Done                | Initial Entry       |

**2. Subcategory of Clinical Event:**

| Date   | Location        | User                | Value                                | Reason              |
|--|-----------------|---------------------|--------------------------------------|---------------------|
| Nov-26-2020 15:40:47<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>Not Applicable | Initial Entry       |
| Nov-24-2020 11:18:19<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u>                   | Transcription Error |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History**Form Version:** 17-Jul-2020 21:55**Form Status:** Data Complete, Deleted, Verified**Site No:** 1217**Site Name:** (1217) Kocaeli University Faculty of Medicine**Subject No:** 12171044**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11**\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\***

|  |                 |                               |   |   |
|--|-----------------|-------------------------------|---|---|
| Nov-23-2020 16:02:01<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>SIGNIFICANT ACUTE HEPATIC D<br>YSFUNCTION | Initial Entry   |
| Nov-23-2020 15:53:57<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b>  | Initial Entry   |
| Nov-16-2020 16:47:25<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b><br>Not Applicable                            | Initial Entry   |
| Nov-16-2020 16:46:53<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b>  | Transcription Error   |
| Nov-16-2020 16:45:48<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b><br>SIGNIFICANT ACUTE HEPATIC D<br>YSFUNCTION | Initial Entry   |
| Nov-16-2020 16:45:12<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b>  | Initial Entry   |
| Nov-16-2020 16:35:09<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b)<br>(4),<br>(b)<br>(6)     | Query 1: Closed   | Response satisfies<br>query   |
| Nov-16-2020 16:31:57<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | Query 1: Answered   | updated   |
| Nov-16-2020 16:30:55<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b><br>Not Applicable                            | Initial Entry   |
| Nov-14-2020 02:41:42<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b)<br>(4),<br>(b)<br>(6)     | Query 1: Opened   | Clinical Query: Per<br>CRF CRs Section<br>8.31, this CRF should<br>only be completed if<br>subject had significant<br>renal, hepatic or<br>neurological<br>dysfunction. If not,<br>please enter FORM<br>LEVEL comment of<br>Not Applicable. |

**3. Was a diagnosis obtained?**

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-26-2020 15:40:47<br>(UTC+03:00) Istanbul | 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 on Nov/12/2020 **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History**Form Version:** 17-Jul-2020 21:55**Form Status:** Data Complete, Deleted, Verified**Site No:** 1217**Site Name:** (1217) Kocaeli University Faculty of Medicine**Subject No:** 12171044**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11**\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\***

|  |                 |                              |                                      |   |
|--|-----------------|------------------------------|--------------------------------------|---|
| Nov-24-2020 11:19:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)    | Query 2: Closed                      | Close Auto Query  |
| Nov-24-2020 11:19:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Gulsah Sarli<br>(pfe.gsarli) | <b>Data Entry:</b>                   | Transcription Error   |
| Nov-23-2020 16:02:01<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)    | Query 2: Opened                      | Response to "Was a diagnosis obtained?" is No. Please review and update as appropriate. |
| Nov-23-2020 16:02:01<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4)   | <b>Data Entry:</b><br>NO             | Initial Entry   |
| Nov-23-2020 15:53:57<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4)   | <b>Data Entry:</b>                   | Initial Entry   |
| Nov-16-2020 16:47:25<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)          | <b>Data Entry:</b><br>Not Applicable | Initial Entry   |
| Nov-16-2020 16:47:03<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)    | Query 1: Closed                      | Close Auto Query  |
| Nov-16-2020 16:47:03<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)          | <b>Data Entry:</b>                   | Transcription Error   |
| Nov-16-2020 16:45:48<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)    | Query 1: Opened                      | Response to "Was a diagnosis obtained?" is No. Please review and update as appropriate. |
| Nov-16-2020 16:45:48<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)          | <b>Data Entry:</b><br>NO             | Initial Entry   |
| Nov-16-2020 16:45:12<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)          | <b>Data Entry:</b>                   | Initial Entry   |
| Nov-16-2020 16:31:11<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)          | <b>Data Entry:</b><br>Not Applicable | Initial Entry   |

**4. Toxicity Grade:**

| Date   | Location        | User                | Value                                | Reason              |
|--|-----------------|---------------------|--------------------------------------|---------------------|
| Nov-26-2020 15:40:47<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry       |
| Nov-24-2020 11:19:11                         | ACV0PFEINFP6000 | (b) (4), (b) (6)    | <b>Data Entry:</b>                   | Transcription Error |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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

|  |                 |                            |                                      |                     |
|--|-----------------|----------------------------|--------------------------------------|---------------------|
| (UTC+03:00) Istanbul                         |                 | (b) (4), (b) (6)           |                                      |                     |
| Nov-23-2020 16:02:01<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>1              | Initial Entry       |
| Nov-23-2020 15:53:57<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b>                   | Initial Entry       |
| Nov-16-2020 16:47:25<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br>Not Applicable | Initial Entry       |
| Nov-16-2020 16:47:16<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b>                   | Transcription Error |
| Nov-16-2020 16:45:48<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br>1              | Initial Entry       |
| Nov-16-2020 16:45:12<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b>                   | Initial Entry       |
| Nov-16-2020 16:31:11<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br>Not Applicable | Initial Entry       |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

**Form Version:** 10-Oct-2020 15:58

**Form Status:**

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Date   | Location        | User                | Value        | Reason |
|--|-----------------|---------------------|--------------|--------|
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Form Created |        |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

**Form Version:** 10-Oct-2020 15:58

**Form Status:**

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Date   | Location        | User                | Value        | Reason |
|--|-----------------|---------------------|--------------|--------|
| Nov-17-2020 15:57:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Form Created |        |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

**Form Version:** 10-Oct-2020 15:58

**Form Status:**

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Date   | Location        | User                          | Value        | Reason |
|--|-----------------|-------------------------------|--------------|--------|
| Nov-23-2020 16:36:15<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Created |        |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

**Form Version:** 10-Oct-2020 15:58

**Form Status:**

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Date   | Location        | User                          | Value        | Reason |
|--|-----------------|-------------------------------|--------------|--------|
| Nov-23-2020 16:43:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Created |        |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

**Form Version:** 10-Oct-2020 15:58

**Form Status:**

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Date   | Location        | User                          | Value        | Reason |
|--|-----------------|-------------------------------|--------------|--------|
| Dec-03-2020 10:15:40<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Created |        |

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Lab Panel:**

| Date   | Location        | User                    | Value                                    | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>CLINICAL CHEMISTRY | Initial Entry |

**2. Laboratory Name and Address**

| Date   | Location        | User                      | Value  | Reason  |
|--|-----------------|---------------------------|--|---|
| Dec-02-2020 19:05:17<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 2: Closed  | Data updated.   |
| Dec-02-2020 16:15:52<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 2: Answered  | Changed Information   |
| Dec-02-2020 16:15:52<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>Kocaeli Universitesi Arastirma ve Uygulama Hastanesi Merkez Laboratuvari, Umuttepe 41380 Kocaeli ,TURKEY                   | Changed Information   |
| Dec-02-2020 14:12:56<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 2: Opened  | DM RQ1 :A carriage return is still identified, Please click into the enterable page and press delete and backspace multiple times to remove the characters. Do not press enter key, just type lab name all in single line with comma separated. |
| Nov-17-2020 09:00:31<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Closed  | Response satisfies query  |
| Nov-16-2020 16:54:25<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>Lab Name:Kocaeli Universitesi Arastirma ve Uygulama Hastanesi Merkez Laboratuvari, Address: Umuttepe 41380 Kocaeli ,TURKEY | Transcription Error   |
| Nov-16-2020 16:49:19<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Answered  | Transcription Error   |
| Nov-16-2020 16:49:19<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>Addres:Kocaeli Universitesi Arastir  | Transcription Error   |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |                 |                     |  |   |
|--|-----------------|---------------------|--|---|
|  |                 |                     | ma ve Uygulama Hastanesi PCR Lab oratuari  |   |
| Nov-15-2020 20:15:52<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Opened  | DM :A carriage return is identified, please do not press enter key, just type lab name all in single line with comma separated. |
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Adres:Kocaeli Universitesi Arastirma ve Uygulama Hastanesi PCR Lab oratuari<br>Name:Kocaeli Universitesi Arastirma ve Uygulama Hastanesi PCR Laboratuari | Initial Entry   |

3. Collection Date:

| Date   | Location        | User                      | Value                             | Reason   |
|--|-----------------|---------------------------|-----------------------------------|--|
| Nov-17-2020 15:14:52<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 2: Closed                   | Close Auto Query   |
| Nov-17-2020 15:14:24<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 2: Opened                   | Collection date is updated, but both results and NOT DONE is marked. Please clarify.   |
| Nov-16-2020 12:08:55<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Closed                   | Close Auto Query   |
| Nov-16-2020 11:52:37<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Opened                   | Collection Date is before Date of First Symptom Started on the Signs and Symptoms form in the same visit. Please review and update as appropriate. |
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>Nov/10/2020 | Initial Entry  |

4. Specimen Type:

| Date   | Location        | User                    | Value                       | Reason        |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>BLOOD | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.a

| Date   | Location        | User                    | Value   | Reason              |
|--|-----------------|-------------------------|---|---------------------|
| Nov-16-2020 12:08:09<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 329<br><b>Test::</b> C Reactive Protein_PX329<br><b>Result::</b> 6.56<br><b>Not Done::</b><br><b>Lab Normal Range:</b> Low<br>0<br><br>High<br>5<br><br>Unit<br>mg/L | Transcription Error |
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 329<br><b>Test::</b> C Reactive Protein_PX329<br><b>Result::</b> 6.5<br><b>Not Done::</b><br><b>Lab Normal Range:</b> Low<br>0<br><br>High<br>5                      | Initial Entry       |

5.a Sponsor ID:

| Date   | Location        | User                    | Value                     | Reason        |
|--|-----------------|-------------------------|---------------------------|---------------|
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>329 | Initial Entry |

5.a Test:

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>C Reactive Protein_PX329 | Initial Entry |

5.a Result:

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

| Date   | Location        | User                      | Value                      | Reason   |
|--|-----------------|---------------------------|----------------------------|--|
| Nov-16-2020 12:08:09<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Closed            | Close Auto Query   |
| Nov-16-2020 12:08:09<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>6.56 | Transcription Error  |
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Opened            | Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm. |
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>6.5  | Initial Entry  |

5.a Not Done:

| Date   | Location        | User                | Value             | Reason  |
|--|-----------------|---------------------|-------------------|---|
| Nov-17-2020 18:36:40<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Closed   | Response satisfies query                            |
| Nov-17-2020 15:17:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Answered | updated   |
| Nov-16-2020 20:42:01<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Opened   | please review and correct all lab results and units |

5.a LNMT

| Date   | Location        | User                | Value   | Reason              |
|--|-----------------|---------------------|---|---------------------|
| Nov-16-2020 12:08:09<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Low<br>0<br><br>High<br>5<br><br>Unit<br>mg/L | Transcription Error |
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Low<br>0                                      | Initial Entry       |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

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Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |           |  |
|--|--|--|-----------|--|
|  |  |  | High<br>5 |  |
|--|--|--|-----------|--|

5.b

| Date   | Location        | User                    | Value  | Reason              |
|--|-----------------|-------------------------|--|---------------------|
| Nov-17-2020 15:13:32<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 30<br><b>Test::</b> Alanine Aminotransferase_PX30<br><b>Result::</b> 43.2<br><b>Not Done::</b><br><b>Lab Normal Range:</b> Low 0<br>High 50<br>Unit U/L | Transcription Error |
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 30<br><b>Test::</b> Alanine Aminotransferase_PX30<br><b>Result::</b> 43<br><b>Not Done::</b><br><b>Lab Normal Range:</b> Low 0<br>High 50<br>Unit U/L   | Initial Entry       |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.b Sponsor ID:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>30 | Initial Entry |

5.b Test:

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Alanine Aminotransferase_PX30 | Initial Entry |

5.b Result:

| Date   | Location        | User                | Value                      | Reason              |
|--|-----------------|---------------------|----------------------------|---------------------|
| Nov-17-2020 15:13:32<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>43.2 | Transcription Error |
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>43   | Initial Entry       |

5.b LNMT

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Low<br>0<br><br>High<br>50<br><br>Unit<br>U/L | Initial Entry |

5.c

| Date   | Location        | User                | Value   | Reason              |
|--|-----------------|---------------------|---|---------------------|
| Nov-17-2020 15:13:55<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sponsor-Define d Identifier:</b><br><b>Test::</b> Aspartate Aminotransferase_PX28<br><b>Result::</b> 28.9<br><b>Not Done::</b> | Transcription Error |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1217

**Subject No:** 12171044

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

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

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

|   |                 |                      |   |               |
|---|-----------------|----------------------|---|---------------|
|   |                 |                      | <b>Lab Normal Range:</b> <i>Low</i><br>0<br><i>High</i><br>50<br><i>Unit</i><br>U/L   |               |
| Nov-13-2020 11:39:41 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Aspartate Aminotransferase_PX28<br><b>Result::</b> 28<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>0<br><i>High</i><br>50<br><i>Unit</i><br>U/L | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.c Sponsor ID:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>28 | Initial Entry |

5.c Test:

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Aspartate Aminotransferase_PX28 | Initial Entry |

5.c Result:

| Date   | Location        | User                | Value                      | Reason              |
|--|-----------------|---------------------|----------------------------|---------------------|
| Nov-17-2020 15:13:55<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>28.9 | Transcription Error |
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>28   | Initial Entry       |

5.c LNMT

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Low<br>0<br><br>High<br>50<br><br>Unit<br>U/L | Initial Entry |

5.d

| Date   | Location        | User                | Value   | Reason              |
|--|-----------------|---------------------|---|---------------------|
| Nov-17-2020 15:14:52<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 35<br><b>Test::</b> Alkaline Phosphatase_PX35<br><b>Result::</b> 74<br><b>Not Done::</b> | Transcription Error |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1217

**Subject No:** 12171044

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

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

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

|   |                 |                      |   |               |
|---|-----------------|----------------------|---|---------------|
|   |                 |                      | <b>Lab Normal Range:</b> <i>Low</i> 30<br><i>High</i> 120<br><i>Unit</i> U/L  |               |
| Nov-17-2020 15:14:24 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)     | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Alkaline Phosphate_PX35<br><b>Result::</b> 74<br><b>Not Done::</b> NOT DONE<br><b>Lab Normal Range:</b> <i>Low</i> 30<br><i>High</i> 120<br><i>Unit</i> U/L | Initial Entry |
| Nov-13-2020 11:39:41 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Alkaline Phosphate_PX35<br><b>Result::</b><br><b>Not Done::</b> NOT DONE<br><b>Lab Normal Range:</b>  | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)



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Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.d Sponsor ID:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>35 | Initial Entry |

5.d Test:

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Alkaline Phosphatase_PX35 | Initial Entry |

5.d Result:

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-17-2020 15:14:24<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>74 | Initial Entry |

5.d Not Done:

| Date   | Location        | User                | Value                          | Reason              |
|--|-----------------|---------------------|--------------------------------|---------------------|
| Nov-17-2020 15:14:52<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b>             | Transcription Error |
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NOT DONE | Initial Entry       |

5.d LNMT

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-17-2020 15:14:24<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Low<br>30<br><br>High<br>120<br><br>Unit<br>U/L | Initial Entry |

5.e

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

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

|  |                 |                         |   |               |
|--|-----------------|-------------------------|---|---------------|
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACVOPFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Bilirubin_PX<br>21<br><b>Result::</b> 0.47<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>0.3<br><br><i>High</i><br>1.2<br><br><i>Unit</i><br>mg/dL | Initial Entry |
|--|-----------------|-------------------------|---|---------------|

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.e Sponsor ID:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>21 | Initial Entry |

5.e Test:

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Bilirubin_PX21 | Initial Entry |

5.e Result:

| Date   | Location        | User                | Value                      | Reason        |
|--|-----------------|---------------------|----------------------------|---------------|
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>0.47 | Initial Entry |

5.e LNMT

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><i>Low</i><br>0.3<br><br><i>High</i><br>1.2<br><br><i>Unit</i><br>mg/dL | Initial Entry |

5.f

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Blood Urea Nitrogen_PX47<br><b>Result::</b><br><b>Not Done::</b> NOT DONE<br><b>Lab Normal Range:</b> | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.f Sponsor ID:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>47 | Initial Entry |

5.f Test:

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Blood Urea Nitrogen_PX47 | Initial Entry |

5.f Not Done:

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NOT DONE | Initial Entry |

5.g

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Creatinine_P X48<br><b>Result::</b> 0.86<br><b>Not Done::</b><br><b>Lab Normal Range:</b> Low 0.67<br>High 1.17<br>Unit mg/dL | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.g Sponsor ID:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>48 | Initial Entry |

5.g Test:

| Date   | Location        | User                | Value                                 | Reason        |
|--|-----------------|---------------------|---------------------------------------|---------------|
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>Creatinine_PX48 | Initial Entry |

5.g Result:

| Date   | Location        | User                | Value                      | Reason        |
|--|-----------------|---------------------|----------------------------|---------------|
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>0.86 | Initial Entry |

5.g LNMT

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-13-2020 11:39:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br><i>Low</i><br>0.67<br><br><i>High</i><br>1.17<br><br><i>Unit</i><br>mg/dL | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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1. Lab Panel:

| Date   | Location        | User                    | Value                                    | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Nov-17-2020 15:57:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>CLINICAL CHEMISTRY | Initial Entry |

2. Laboratory Name and Address

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-17-2020 15:57:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Lab Name:Kocaeli Universitesi Arastir<br>ma ve Uygulama Hastanesi Merkez Lab<br>oratuvari, Address: Umuttepe 41380 Ko<br>caeli ,TURKEY | Initial Entry |

3. Collection Date:

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Nov-17-2020 15:57:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/16/2020 | Initial Entry |

4. Specimen Type:

| Date   | Location        | User                    | Value                       | Reason        |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Nov-17-2020 15:57:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>BLOOD | Initial Entry |

5.a

| Date   | Location        | User                          | Value   | Reason              |
|--|-----------------|-------------------------------|---|---------------------|
| Dec-03-2020 08:44:57<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 329<br><b>Test::</b> C Reactive Protei<br>n_PX329<br><b>Result::</b> 4.60<br><b>Not Done::</b> | Changed Information |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|   |                 |                      |   |                     |
|---|-----------------|----------------------|---|---------------------|
|   |                 |                      | <b>Lab Normal Range:</b><br><i>Low</i><br>0<br><br><i>High</i><br>5<br><br><i>Unit</i><br>mg/L  |                     |
| Nov-17-2020 17:03:48 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 329<br><b>Test::</b> C Reactive Protein_PX329<br><b>Result::</b> 4,60<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 0<br><br><i>High</i> 5<br><br><i>Unit</i> mg/L | Initial Entry       |
| Nov-17-2020 17:02:57 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> C Reactive Protein_PX329<br><b>Result::</b><br><b>Not Done::</b><br><b>Lab Normal Range:</b>  | Transcription Error |
| Nov-17-2020 15:57:51 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 329<br><b>Test::</b> C Reactive Protein_PX329<br><b>Result::</b><br><b>Not Done::</b> NOT DONE<br><b>Lab Normal Range:</b>   | Initial Entry       |

5.a Sponsor ID:

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

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |                 |                         |                           |                     |
|--|-----------------|-------------------------|---------------------------|---------------------|
| Nov-17-2020 17:03:48<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>329 | Initial Entry       |
| Nov-17-2020 17:02:57<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b>        | Transcription Error |
| Nov-17-2020 15:57:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>329 | Initial Entry       |

5.a Test:

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-17-2020 15:57:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>C Reactive Protein_PX329 | Initial Entry |

5.a Result:

| Date   | Location        | User                       | Value                      | Reason   |
|--|-----------------|----------------------------|----------------------------|--|
| Dec-03-2020 12:28:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Balaji Prabu R<br>(b) (4)  | Query 1: Closed            | Response satisfies query                         |
| Dec-03-2020 08:44:57<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)  | Query 1: Answered          | Changed Information                              |
| Dec-03-2020 08:44:57<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>4.60 | Changed Information                              |
| Dec-03-2020 02:38:48<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Erica Weaver<br>(b) (4)    | Query 1: Opened            | Please replace the comma with a decimal. Thanks. |
| Nov-17-2020 17:03:48<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br>4,60 | Initial Entry                                    |

5.a Not Done:

| Date   | Location        | User                | Value                          | Reason              |
|--|-----------------|---------------------|--------------------------------|---------------------|
| Nov-17-2020 17:02:57<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b>             | Transcription Error |
| Nov-17-2020 15:57:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NOT DONE | Initial Entry       |

5.a LNMT

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

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |                 |                     |  |               |
|--|-----------------|---------------------|--|---------------|
| Nov-17-2020 17:03:48<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><i>Low</i><br>0<br><i>High</i><br>5<br><br><i>Unit</i><br>mg/L | Initial Entry |
|--|-----------------|---------------------|--|---------------|

5.b

| Date   | Location        | User                       | Value   | Reason              |
|--|-----------------|----------------------------|---|---------------------|
| Dec-03-2020 08:45:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 30<br><b>Test::</b> Alanine Aminotransferase_PX30<br><b>Result::</b> 101.5<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>0<br><br><i>High</i><br>50<br><br><i>Unit</i><br>U/L | Changed Information |
| Nov-17-2020 15:57:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc)    | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 30<br><b>Test::</b> Alanine Aminotransferase_PX30<br><b>Result::</b> 101,5<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>0<br><br><i>High</i><br>50<br><br><i>Unit</i><br>U/L | Initial Entry       |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.b Sponsor ID:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-17-2020 15:57:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>30 | Initial Entry |

5.b Test:

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-17-2020 15:57:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>Alanine Aminotransferase_PX30 | Initial Entry |

5.b Result:

| Date   | Location        | User                       | Value                       | Reason   |
|--|-----------------|----------------------------|-----------------------------|--|
| Dec-03-2020 12:28:46<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Balaji Prabu R<br>(b) (4)  | Query 1: Closed             | Response satisfies query                         |
| Dec-03-2020 08:45:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)  | Query 1: Answered           | Changed Information                              |
| Dec-03-2020 08:45:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <u>Data Entry:</u><br>101.5 | Changed Information                              |
| Dec-03-2020 02:39:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Erica Weaver<br>(b) (4)    | Query 1: Opened             | Please replace the comma with a decimal. Thanks. |
| Nov-17-2020 15:57:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <u>Data Entry:</u><br>101,5 | Initial Entry                                    |

5.b LNMT

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-17-2020 15:57:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br><i>Low</i><br>0<br><br><i>High</i><br>50<br><br><i>Unit</i><br>U/L | Initial Entry |

5.c

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

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1217

**Subject No:** 12171044

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

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

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

|  |                 |                               |   |                     |
|--|-----------------|-------------------------------|---|---------------------|
| Dec-03-2020 08:45:49<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><b>Sponsor-Define d Identifier:</b> 28<br><b>Test::</b> Aspartate Aminotransferase_PX28<br><b>Result::</b> 49.0<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>0<br><br><i>High</i><br>50<br><br><i>Unit</i><br>U/L | Changed Information |
| Nov-17-2020 15:57:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc)       | <b>Data Entry:</b><br><b>Sponsor-Define d Identifier:</b> 28<br><b>Test::</b> Aspartate Aminotransferase_PX28<br><b>Result::</b> 49,0<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>0<br><br><i>High</i><br>50<br><br><i>Unit</i><br>U/L | Initial Entry       |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

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Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.c Sponsor ID:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-17-2020 15:57:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>28 | Initial Entry |

5.c Test:

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-17-2020 15:57:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>Aspartate Aminotransferase_PX28 | Initial Entry |

5.c Result:

| Date   | Location        | User                       | Value                      | Reason   |
|--|-----------------|----------------------------|----------------------------|--|
| Dec-03-2020 12:29:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Balaji Prabu R<br>(b) (4)  | Query 1: Closed            | Response satisfies query                         |
| Dec-03-2020 08:45:49<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)  | Query 1: Answered          | Changed Information                              |
| Dec-03-2020 08:45:49<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <u>Data Entry:</u><br>49.0 | Changed Information                              |
| Dec-03-2020 02:39:10<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Erica Weaver<br>(b) (4)    | Query 1: Opened            | Please replace the comma with a decimal. Thanks. |
| Nov-17-2020 15:57:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <u>Data Entry:</u><br>49,0 | Initial Entry                                    |

5.c LNMT

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-17-2020 15:57:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br><i>Low</i><br>0<br><br><i>High</i><br>50<br><br><i>Unit</i><br>U/L | Initial Entry |

5.d

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

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

|  |                 |                         |  |               |
|--|-----------------|-------------------------|--|---------------|
| Nov-17-2020 15:57:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Alkaline Phosphatase_PX35<br><b>Result::</b> 50<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 30<br><br><i>High</i> 120<br><br><i>Unit</i> U/L | Initial Entry |
|--|-----------------|-------------------------|--|---------------|

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.d Sponsor ID:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-17-2020 15:57:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>35 | Initial Entry |

5.d Test:

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-17-2020 15:57:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Alkaline Phosphatase_PX35 | Initial Entry |

5.d Result:

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-17-2020 15:57:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>50 | Initial Entry |

5.d LNMT

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-17-2020 15:57:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><i>Low</i><br>30<br><br><i>High</i><br>120<br><br><i>Unit</i><br>U/L | Initial Entry |

5.e

| Date   | Location        | User                          | Value   | Reason              |
|--|-----------------|-------------------------------|---|---------------------|
| Dec-03-2020 08:46:57<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Bilirubin_P<br>X21<br><b>Result::</b> 0.54<br><b>Not Done::</b> | Changed Information |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |                 |                            |   |                     |
|--|-----------------|----------------------------|---|---------------------|
|  |                 |                            | <b>Lab Normal Range:</b> <i>Low</i><br>0.3<br><br><i>High</i><br>1.2<br><br><i>Unit</i><br>mg/dL  |                     |
| Dec-03-2020 08:46:22<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 21<br><b>Test::</b> Bilirubin_P X21<br><b>Result::</b> 0.54<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>0,3<br><br><i>High</i><br>1,2<br><br><i>Unit</i><br>mg/dL | Changed Information |
| Nov-17-2020 15:57:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc)    | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 21<br><b>Test::</b> Bilirubin_P X21<br><b>Result::</b> 0,54<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>0,3<br><br><i>High</i><br>1,2<br><br><i>Unit</i><br>mg/dL | Initial Entry       |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

**5.e Sponsor ID:**

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-17-2020 15:57:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>21 | Initial Entry |

**5.e Test:**

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-17-2020 15:57:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Bilirubin_PX21 | Initial Entry |

**5.e Result:**

| Date   | Location        | User                          | Value                      | Reason   |
|--|-----------------|-------------------------------|----------------------------|--|
| Dec-03-2020 12:29:15<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Balaji Prabu R<br>(b) (4)     | Query 1: Closed            | Response satisfies query                         |
| Dec-03-2020 08:46:22<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)     | Query 1: Answered          | Changed Information                              |
| Dec-03-2020 08:46:22<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>0.54 | Changed Information                              |
| Dec-03-2020 02:39:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Erica Weaver<br>(b) (4)       | Query 1: Opened            | Please replace the comma with a decimal. Thanks. |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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5.e Result:

| Date   | Location        | User                | Value                      | Reason        |
|--|-----------------|---------------------|----------------------------|---------------|
| Nov-17-2020 15:57:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>0,54 | Initial Entry |

5.e LNMT

| Date   | Location        | User                       | Value   | Reason   |
|--|-----------------|----------------------------|---|--|
| Dec-03-2020 12:29:30<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Balaji Prabu R<br>(b) (4)  | Query 1: Closed   | Response satisfies query                         |
| Dec-03-2020 08:46:57<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)  | Query 1: Answered   | Changed Information                              |
| Dec-03-2020 08:46:57<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br><i>Low</i><br>0.3<br><br><i>High</i><br>1.2<br><br><i>Unit</i><br>mg/dL | Changed Information                              |
| Dec-03-2020 02:40:08<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Erica Weaver<br>(b) (4)    | Query 1: Opened   | Please replace the comma with a decimal. Thanks. |
| Nov-17-2020 15:57:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br><i>Low</i><br>0,3<br><br><i>High</i><br>1,2<br><br><i>Unit</i><br>mg/dL | Initial Entry                                    |

5.f

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Nov-17-2020 15:57:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined I 47<br/>dentifier:</b> | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Test::</b> Blood Urea Nitrogen_PX47<br><b>Result::</b> 13<br><b>Not Done::</b><br><b>Lab Normal Range:</b> Low 7<br>High 20<br>Unit mg/dL |  |
|--|--|--|--|--|

5.f Sponsor ID:

| Date                                      | Location        | User                 | Value                 | Reason        |
|---|-----------------|----------------------|-----------------------|---------------|
| Nov-17-2020 15:57:51 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b> 47 | Initial Entry |

5.f Test:

| Date                                      | Location        | User             | Value                                       | Reason        |
|---|-----------------|------------------|---|---------------|
| Nov-17-2020 15:57:51 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b> Blood Urea Nitrogen_PX47 | Initial Entry |

5.f Result:

| Date                                      | Location        | User             | Value                 | Reason        |
|---|-----------------|------------------|-----------------------|---------------|
| Nov-17-2020 15:57:51 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b> 13 | Initial Entry |

5.f LNMT

| Date                                      | Location        | User             | Value   | Reason        |
|---|-----------------|------------------|---|---------------|
| Nov-17-2020 15:57:51 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b> Low 7<br>High 20<br>Unit mg/dL | Initial Entry |

5.g

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

| Date   | Location        | User                       | Value   | Reason              |
|--|-----------------|----------------------------|---|---------------------|
| Dec-03-2020 08:47:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 48<br><b>Test::</b> Creatinine_P X48<br><b>Result::</b> 0.76<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 0.67<br><i>High</i> 1.17<br><i>Unit</i> mg/dL | Changed Information |
| Dec-03-2020 08:47:22<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 48<br><b>Test::</b> Creatinine_P X48<br><b>Result::</b> 0.76<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 0,67<br><i>High</i> 1,17<br><i>Unit</i> mg/dL | Changed Information |
| Nov-17-2020 15:57:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc)    | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 48<br><b>Test::</b> Creatinine_P X48<br><b>Result::</b> 0,76<br><b>Not Done::</b>  | Initial Entry       |

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1217

**Subject No:** 12171044

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

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

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Lab Normal Range:</b> <i>Low</i><br>0,67<br><br><i>High</i><br>1,17<br><br><i>Unit</i><br>mg/dL |  |
|--|--|--|--|--|

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.g Sponsor ID:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-17-2020 15:57:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>48 | Initial Entry |

5.g Test:

| Date   | Location        | User                | Value                                 | Reason        |
|--|-----------------|---------------------|---------------------------------------|---------------|
| Nov-17-2020 15:57:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>Creatinine_PX48 | Initial Entry |

5.g Result:

| Date   | Location        | User                       | Value                      | Reason   |
|--|-----------------|----------------------------|----------------------------|--|
| Dec-03-2020 12:29:46<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Balaji Prabu R<br>(b) (4)  | Query 1: Closed            | Response satisfies query                         |
| Dec-03-2020 08:47:22<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)  | Query 1: Answered          | Changed Information                              |
| Dec-03-2020 08:47:22<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <u>Data Entry:</u><br>0.76 | Changed Information                              |
| Dec-03-2020 02:39:33<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Erica Weaver<br>(b) (4)    | Query 1: Opened            | Please replace the comma with a decimal. Thanks. |
| Nov-17-2020 15:57:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <u>Data Entry:</u><br>0,76 | Initial Entry                                    |

5.g LNMT

| Date   | Location        | User                       | Value  | Reason                   |
|--|-----------------|----------------------------|--|--------------------------|
| Dec-03-2020 12:30:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Balaji Prabu R<br>(b) (4)  | Query 1: Closed  | Response satisfies query |
| Dec-03-2020 08:47:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)  | Query 1: Answered  | Changed Information      |
| Dec-03-2020 08:47:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <u>Data Entry:</u><br><i>Low</i><br>0.67<br><br><i>High</i><br>1.17<br><br><i>Unit</i> | Changed Information      |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1217

**Subject No:** 12171044

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

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

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

|  |                 |                         | mg/dL   |  |
|--|-----------------|-------------------------|---|--|
| Dec-03-2020 02:39:55<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Erica Weaver<br>(b) (4) | Query 1: Opened   | Please replace the comma with a decimal. Thanks. |
| Nov-17-2020 15:57:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | <b>Data Entry:</b><br><i>Low</i><br>0,67<br><i>High</i><br>1,17<br><i>Unit</i><br>mg/dL | Initial Entry                                    |

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Lab Panel:**

| Date   | Location        | User                    | Value                                    | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Nov-23-2020 16:36:15<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>CLINICAL CHEMISTRY | Initial Entry |

**2. Laboratory Name and Address**

| Date   | Location        | User                          | Value   | Reason        |
|--|-----------------|-------------------------------|---|---------------|
| Nov-23-2020 16:36:15<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Lab Name:Kocaeli Universitesi Arastirma ve Uygulama Hastanesi Merkez Laboratuvari, Address: Umuttepe 413 80 Kocaeli ,TURKEY | Initial Entry |

**3. Collection Date:**

| Date   | Location        | User                          | Value                             | Reason        |
|--|-----------------|-------------------------------|-----------------------------------|---------------|
| Nov-23-2020 16:36:15<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Nov/20/2020 | Initial Entry |

**4. Specimen Type:**

| Date   | Location        | User                    | Value                       | Reason        |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Nov-23-2020 16:36:15<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>BLOOD | Initial Entry |

**5.a**

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Nov-23-2020 16:36:15<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Sponsor-Defined Identifier:<br>Test:: C Reactive Protein<br>_PX329<br>Result:: 44.77<br>Not Done:: | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Lab Normal Range:</b><br><i>Low</i><br>0<br><br><i>High</i><br>5<br><br><i>Unit</i><br>mg/L |  |
|--|--|--|--|--|

5.a Sponsor ID:

| Date                                      | Location        | User                 | Value                     | Reason        |
|---|-----------------|----------------------|---------------------------|---------------|
| Nov-23-2020 16:36:15 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br>329 | Initial Entry |

5.a Test:

| Date                                      | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Nov-23-2020 16:36:15 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b><br>C Reactive Protein_PX329 | Initial Entry |

5.a Result:

| Date                                      | Location        | User                    | Value                       | Reason        |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Nov-23-2020 16:36:15 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b><br>44.77 | Initial Entry |

5.a LNMT

| Date                                      | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Nov-23-2020 16:36:15 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b><br><i>Low</i><br>0<br><br><i>High</i><br>5<br><br><i>Unit</i><br>mg/L | Initial Entry |

5.b

| Date                                      | Location        | User                 | Value              | Reason        |
|---|-----------------|----------------------|--------------------|---------------|
| Nov-23-2020 16:36:15 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b> | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Sponsor-Defined 30 Identifier:</b><br><b>Test::</b> Alanine Aminotransferase_PX30<br><b>Result::</b> 160.8<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 0<br><i>High</i> 50<br><i>Unit</i> U/L |  |
|--|--|--|--|--|

5.b Sponsor ID:

| Date                                      | Location        | User                 | Value                 | Reason        |
|---|-----------------|----------------------|-----------------------|---------------|
| Nov-23-2020 16:36:15 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b> 30 | Initial Entry |

5.b Test:

| Date                                      | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Nov-23-2020 16:36:15 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b> Alanine Aminotransferase_PX30 | Initial Entry |

5.b Result:

| Date                                      | Location        | User                    | Value                    | Reason        |
|---|-----------------|-------------------------|--------------------------|---------------|
| Nov-23-2020 16:36:15 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b> 160.8 | Initial Entry |

5.b LNMT

| Date                                      | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Nov-23-2020 16:36:15 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b> <i>Low</i> 0<br><i>High</i> 50<br><i>Unit</i> U/L | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

5.c

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-23-2020 16:36:15<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 28<br><b>Test::</b> Aspartate Aminotransferase_PX28<br><b>Result::</b> 66.7<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 0<br><br><i>High</i> 50<br><br><i>Unit</i> U/L | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

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Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.c Sponsor ID:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-23-2020 16:36:15<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>28 | Initial Entry |

5.c Test:

| Date   | Location        | User                          | Value   | Reason        |
|--|-----------------|-------------------------------|---|---------------|
| Nov-23-2020 16:36:15<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Aspartate Aminotransferase_PX28 | Initial Entry |

5.c Result:

| Date   | Location        | User                          | Value                      | Reason        |
|--|-----------------|-------------------------------|----------------------------|---------------|
| Nov-23-2020 16:36:15<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>66.7 | Initial Entry |

5.c LNMT

| Date   | Location        | User                          | Value  | Reason        |
|--|-----------------|-------------------------------|--|---------------|
| Nov-23-2020 16:36:15<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><br><i>Low</i><br>0<br><br><i>High</i><br>50<br><br><i>Unit</i><br>U/L | Initial Entry |

5.d

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Nov-23-2020 16:36:15<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Alkaline Phosphatase_PX35<br><b>Result::</b> 53<br><b>Not Done::</b> | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Lab Normal Range:</b><br><i>Low</i><br>30<br><br><i>High</i><br>120<br><br><i>Unit</i><br>U/L |  |
|--|--|--|--|--|

5.d Sponsor ID:

| Date                                      | Location        | User                 | Value                    | Reason        |
|---|-----------------|----------------------|--------------------------|---------------|
| Nov-23-2020 16:36:15 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br>35 | Initial Entry |

5.d Test:

| Date                                      | Location        | User                    | Value   | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Nov-23-2020 16:36:15 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b><br>Alkaline Phosphatase_PX35 | Initial Entry |

5.d Result:

| Date                                      | Location        | User                    | Value                    | Reason        |
|---|-----------------|-------------------------|--------------------------|---------------|
| Nov-23-2020 16:36:15 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b><br>53 | Initial Entry |

5.d LNMT

| Date                                      | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Nov-23-2020 16:36:15 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b><br><i>Low</i><br>30<br><br><i>High</i><br>120<br><br><i>Unit</i><br>U/L | Initial Entry |

5.e

| Date                                      | Location        | User                 | Value              | Reason        |
|---|-----------------|----------------------|--------------------|---------------|
| Nov-23-2020 16:36:15 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b> | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | <b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Bilirubin_PX 21<br><b>Result::</b> 0.59<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 0.3<br><br><i>High</i> 1.2<br><br><i>Unit</i> mg/dL |  |
|--|--|--|---|--|

5.e Sponsor ID:

| Date                                      | Location        | User                 | Value                 | Reason        |
|---|-----------------|----------------------|-----------------------|---------------|
| Nov-23-2020 16:36:15 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b> 21 | Initial Entry |

5.e Test:

| Date                                      | Location        | User                    | Value                             | Reason        |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Nov-23-2020 16:36:15 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b> Bilirubin_PX21 | Initial Entry |

5.e Result:

| Date                                      | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Nov-23-2020 16:36:15 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b> 0.59 | Initial Entry |

5.e LNMT

| Date                                      | Location        | User                    | Value   | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Nov-23-2020 16:36:15 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b> <i>Low</i> 0.3<br><br><i>High</i> 1.2<br><br><i>Unit</i> mg/dL | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

5.f

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-23-2020 16:36:15<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Blood Urea Nitrogen_PX47<br><b>Result::</b> 13<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 7<br><i>High</i> 20<br><i>Unit</i> mg/dL | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.f Sponsor ID:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-23-2020 16:36:15<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>47 | Initial Entry |

5.f Test:

| Date   | Location        | User                          | Value  | Reason        |
|--|-----------------|-------------------------------|--|---------------|
| Nov-23-2020 16:36:15<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Blood Urea Nitrogen_PX47 | Initial Entry |

5.f Result:

| Date   | Location        | User                          | Value                    | Reason        |
|--|-----------------|-------------------------------|--------------------------|---------------|
| Nov-23-2020 16:36:15<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>13 | Initial Entry |

5.f LNMT

| Date   | Location        | User                          | Value  | Reason        |
|--|-----------------|-------------------------------|--|---------------|
| Nov-23-2020 16:36:15<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><br><i>Low</i><br>7<br><br><i>High</i><br>20<br><br><i>Unit</i><br>mg/dL | Initial Entry |

5.g

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Nov-23-2020 16:36:15<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Creatinine_P<br>X48<br><b>Result::</b> 0.93<br><b>Not Done::</b> | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Lab Normal Range:</b> <i>Low</i><br>0.67<br><br><i>High</i><br>1.17<br><br><i>Unit</i><br>mg/dL |  |
|--|--|--|--|--|

5.g Sponsor ID:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-23-2020 16:36:15<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>48 | Initial Entry |

5.g Test:

| Date   | Location        | User                          | Value                                 | Reason        |
|--|-----------------|-------------------------------|---------------------------------------|---------------|
| Nov-23-2020 16:36:15<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Creatinine_PX48 | Initial Entry |

5.g Result:

| Date   | Location        | User                          | Value                      | Reason        |
|--|-----------------|-------------------------------|----------------------------|---------------|
| Nov-23-2020 16:36:15<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>0.93 | Initial Entry |

5.g LNMT

| Date   | Location        | User                          | Value   | Reason        |
|--|-----------------|-------------------------------|---|---------------|
| Nov-23-2020 16:36:15<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><i>Low</i><br>0.67<br><br><i>High</i><br>1.17<br><br><i>Unit</i><br>mg/dL | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

[Back to Form](#)

**1. Lab Panel:**

| Date   | Location        | User                    | Value                                    | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Nov-23-2020 16:43:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>CLINICAL CHEMISTRY | Initial Entry |

**2. Laboratory Name and Address**

| Date   | Location        | User                          | Value   | Reason        |
|--|-----------------|-------------------------------|---|---------------|
| Nov-23-2020 16:43:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Lab Name:Kocaeli Universitesi Arastirma ve Uygulama Hastanesi Merkez Laboratuvari, Address: Umuttepe 413 80 Kocaeli ,TURKEY | Initial Entry |

**3. Collection Date:**

| Date   | Location        | User                          | Value                             | Reason        |
|--|-----------------|-------------------------------|-----------------------------------|---------------|
| Nov-23-2020 16:43:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Nov/23/2020 | Initial Entry |

**4. Specimen Type:**

| Date   | Location        | User                    | Value                       | Reason        |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Nov-23-2020 16:43:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>BLOOD | Initial Entry |

**5.a**

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-23-2020 16:43:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Sponsor-Defined Identifier:<br>Test:: C Reactive Protein<br>_PX329<br>Result:: 9.62<br>Not Done:: | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Lab Normal Range:</b><br><i>Low</i><br>0<br><br><i>High</i><br>5<br><br><i>Unit</i><br>mg/L |  |
|--|--|--|--|--|

5.a Sponsor ID:

| Date                                      | Location        | User                 | Value                     | Reason        |
|---|-----------------|----------------------|---------------------------|---------------|
| Nov-23-2020 16:43:51 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br>329 | Initial Entry |

5.a Test:

| Date                                      | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Nov-23-2020 16:43:51 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b><br>C Reactive Protein_PX329 | Initial Entry |

5.a Result:

| Date                                      | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Nov-23-2020 16:43:51 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b><br>9.62 | Initial Entry |

5.a LNMT

| Date                                      | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Nov-23-2020 16:43:51 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b><br><i>Low</i><br>0<br><br><i>High</i><br>5<br><br><i>Unit</i><br>mg/L | Initial Entry |

5.b

| Date                                      | Location        | User                 | Value              | Reason        |
|---|-----------------|----------------------|--------------------|---------------|
| Nov-23-2020 16:43:51 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b> | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Sponsor-Defined 30 Identifier:</b><br><b>Test::</b> Alanine Aminotransferase_PX30<br><b>Result::</b> 219.3<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 0<br><i>High</i> 50<br><i>Unit</i> U/L |  |
|--|--|--|--|--|

5.b Sponsor ID:

| Date                                      | Location        | User                 | Value                 | Reason        |
|---|-----------------|----------------------|-----------------------|---------------|
| Nov-23-2020 16:43:51 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b> 30 | Initial Entry |

5.b Test:

| Date                                      | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Nov-23-2020 16:43:51 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b> Alanine Aminotransferase_PX30 | Initial Entry |

5.b Result:

| Date                                      | Location        | User                    | Value                    | Reason        |
|---|-----------------|-------------------------|--------------------------|---------------|
| Nov-23-2020 16:43:51 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b> 219.3 | Initial Entry |

5.b LNMT

| Date                                      | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Nov-23-2020 16:43:51 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b> <i>Low</i> 0<br><i>High</i> 50<br><i>Unit</i> U/L | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

5.c

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-23-2020 16:43:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 28<br><b>Test::</b> Aspartate Aminotransferase_PX28<br><b>Result::</b> 76.4<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 0<br><br><i>High</i> 50<br><br><i>Unit</i> U/L | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.c Sponsor ID:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-23-2020 16:43:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>28 | Initial Entry |

5.c Test:

| Date   | Location        | User                          | Value   | Reason        |
|--|-----------------|-------------------------------|---|---------------|
| Nov-23-2020 16:43:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Aspartate Aminotransferase_PX28 | Initial Entry |

5.c Result:

| Date   | Location        | User                          | Value                      | Reason        |
|--|-----------------|-------------------------------|----------------------------|---------------|
| Nov-23-2020 16:43:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>76.4 | Initial Entry |

5.c LNMT

| Date   | Location        | User                          | Value  | Reason        |
|--|-----------------|-------------------------------|--|---------------|
| Nov-23-2020 16:43:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><br><i>Low</i><br>0<br><br><i>High</i><br>50<br><br><i>Unit</i><br>U/L | Initial Entry |

5.d

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Nov-23-2020 16:43:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Alkaline Phosphatase_PX35<br><b>Result::</b> 55<br><b>Not Done::</b> | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Lab Normal Range:</b><br><i>Low</i><br>30<br><br><i>High</i><br>120<br><br><i>Unit</i><br>U/L |  |
|--|--|--|--|--|

5.d Sponsor ID:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-23-2020 16:43:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>35 | Initial Entry |

5.d Test:

| Date   | Location        | User                       | Value   | Reason        |
|--|-----------------|----------------------------|---|---------------|
| Nov-23-2020 16:43:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Alkaline Phosphatase_PX35 | Initial Entry |

5.d Result:

| Date   | Location        | User                       | Value                    | Reason        |
|--|-----------------|----------------------------|--------------------------|---------------|
| Nov-23-2020 16:43:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>55 | Initial Entry |

5.d LNMT

| Date   | Location        | User                       | Value  | Reason        |
|--|-----------------|----------------------------|--|---------------|
| Nov-23-2020 16:43:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br><i>Low</i><br>30<br><br><i>High</i><br>120<br><br><i>Unit</i><br>U/L | Initial Entry |

5.e

| Date   | Location        | User                    | Value              | Reason        |
|--|-----------------|-------------------------|--------------------|---------------|
| Nov-23-2020 16:43:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b> | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | <b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Bilirubin_PX 21<br><b>Result::</b> 0.51<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 0.3<br><br><i>High</i> 1.2<br><br><i>Unit</i> mg/dL |  |
|--|--|--|---|--|

5.e Sponsor ID:

| Date                                      | Location        | User                 | Value                 | Reason        |
|---|-----------------|----------------------|-----------------------|---------------|
| Nov-23-2020 16:43:51 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b> 21 | Initial Entry |

5.e Test:

| Date                                      | Location        | User                    | Value                             | Reason        |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Nov-23-2020 16:43:51 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b> Bilirubin_PX21 | Initial Entry |

5.e Result:

| Date                                      | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Nov-23-2020 16:43:51 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b> 0.51 | Initial Entry |

5.e LNMT

| Date                                      | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Nov-23-2020 16:43:51 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b><br><i>Low</i> 0.3<br><br><i>High</i> 1.2<br><br><i>Unit</i> mg/dL | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

5.f

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-23-2020 16:43:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Blood Urea Nitrogen_PX47<br><b>Result::</b> 17<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 7<br><i>High</i> 20<br><i>Unit</i> mg/dL | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.f Sponsor ID:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-23-2020 16:43:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>47 | Initial Entry |

5.f Test:

| Date   | Location        | User                          | Value  | Reason        |
|--|-----------------|-------------------------------|--|---------------|
| Nov-23-2020 16:43:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Blood Urea Nitrogen_PX47 | Initial Entry |

5.f Result:

| Date   | Location        | User                          | Value                    | Reason        |
|--|-----------------|-------------------------------|--------------------------|---------------|
| Nov-23-2020 16:43:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>17 | Initial Entry |

5.f LNMT

| Date   | Location        | User                          | Value  | Reason        |
|--|-----------------|-------------------------------|--|---------------|
| Nov-23-2020 16:43:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><br><i>Low</i><br>7<br><br><i>High</i><br>20<br><br><i>Unit</i><br>mg/dL | Initial Entry |

5.g

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Nov-23-2020 16:43:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Creatinine_P<br>X48<br><b>Result::</b> 0.81<br><b>Not Done::</b> | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Lab Normal Range:</b> <i>Low</i><br>0.67<br><br><i>High</i><br>1.17<br><br><i>Unit</i><br>mg/dL |  |
|--|--|--|--|--|

5.g Sponsor ID:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-23-2020 16:43:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>48 | Initial Entry |

5.g Test:

| Date   | Location        | User                          | Value                                 | Reason        |
|--|-----------------|-------------------------------|---------------------------------------|---------------|
| Nov-23-2020 16:43:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Creatinine_PX48 | Initial Entry |

5.g Result:

| Date   | Location        | User                          | Value                      | Reason        |
|--|-----------------|-------------------------------|----------------------------|---------------|
| Nov-23-2020 16:43:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>0.81 | Initial Entry |

5.g LNMT

| Date   | Location        | User                          | Value   | Reason        |
|--|-----------------|-------------------------------|---|---------------|
| Nov-23-2020 16:43:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><i>Low</i><br>0.67<br><br><i>High</i><br>1.17<br><br><i>Unit</i><br>mg/dL | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

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Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Lab Panel:**

| Date   | Location        | User                    | Value                                    | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Dec-03-2020 10:15:40<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>CLINICAL CHEMISTRY | Initial Entry |

**2. Laboratory Name and Address**

| Date   | Location        | User                          | Value  | Reason        |
|--|-----------------|-------------------------------|--|---------------|
| Dec-03-2020 10:15:40<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Kocaeli Universitesi Arastirma ve Uygulama Hastanesi Merkez Laboratuvarı, Umuttepe 41380 Kocaeli ,TURKEY | Initial Entry |

**3. Collection Date:**

| Date   | Location        | User                          | Value                             | Reason        |
|--|-----------------|-------------------------------|-----------------------------------|---------------|
| Dec-03-2020 10:15:40<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Nov/29/2020 | Initial Entry |

**4. Specimen Type:**

| Date   | Location        | User                    | Value                       | Reason        |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Dec-03-2020 10:15:40<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>BLOOD | Initial Entry |

**5.a**

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Dec-03-2020 10:15:40<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Sponsor-Defined Identifier:<br>Test:: C Reactive Protein<br>_PX329<br>Result:: 1.02<br>Not Done:: | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Lab Normal Range:</b><br><i>Low</i><br>0<br><br><i>High</i><br>5<br><br><i>Unit</i><br>mg/L |  |
|--|--|--|--|--|

5.a Sponsor ID:

| Date   | Location        | User                    | Value                     | Reason        |
|--|-----------------|-------------------------|---------------------------|---------------|
| Dec-03-2020 10:15:40<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>329 | Initial Entry |

5.a Test:

| Date   | Location        | User                       | Value  | Reason        |
|--|-----------------|----------------------------|--|---------------|
| Dec-03-2020 10:15:40<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>C Reactive Protein_PX329 | Initial Entry |

5.a Result:

| Date   | Location        | User                       | Value                      | Reason        |
|--|-----------------|----------------------------|----------------------------|---------------|
| Dec-03-2020 10:15:40<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>1.02 | Initial Entry |

5.a LNMT

| Date   | Location        | User                       | Value  | Reason        |
|--|-----------------|----------------------------|--|---------------|
| Dec-03-2020 10:15:40<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br><i>Low</i><br>0<br><br><i>High</i><br>5<br><br><i>Unit</i><br>mg/L | Initial Entry |

5.b

| Date   | Location        | User                    | Value              | Reason        |
|--|-----------------|-------------------------|--------------------|---------------|
| Dec-03-2020 10:15:40<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b> | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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Form Version: 10-Oct-2020 15:58

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Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Sponsor-Defined 30 Identifier:</b><br><b>Test::</b> Alanine Aminotransferase_PX30<br><b>Result::</b> 187.1<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 0<br><i>High</i> 50<br><i>Unit</i> U/L |  |
|--|--|--|--|--|

5.b Sponsor ID:

| Date                                      | Location        | User                 | Value                 | Reason        |
|---|-----------------|----------------------|-----------------------|---------------|
| Dec-03-2020 10:15:40 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b> 30 | Initial Entry |

5.b Test:

| Date                                      | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Dec-03-2020 10:15:40 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b> Alanine Aminotransferase_PX30 | Initial Entry |

5.b Result:

| Date                                      | Location        | User                    | Value                    | Reason        |
|---|-----------------|-------------------------|--------------------------|---------------|
| Dec-03-2020 10:15:40 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b> 187.1 | Initial Entry |

5.b LNMT

| Date                                      | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Dec-03-2020 10:15:40 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b> <i>Low</i> 0<br><i>High</i> 50<br><i>Unit</i> U/L | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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**Form Version:** 10-Oct-2020 15:58

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

5.c

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Dec-03-2020 10:15:40<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 28<br><b>Test::</b> Aspartate Aminotransferase_PX28<br><b>Result::</b> 36.3<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 0<br><i>High</i> 50<br><i>Unit</i> U/L | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.c Sponsor ID:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Dec-03-2020 10:15:40<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>28 | Initial Entry |

5.c Test:

| Date   | Location        | User                       | Value   | Reason        |
|--|-----------------|----------------------------|---|---------------|
| Dec-03-2020 10:15:40<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Aspartate Aminotransferase_PX28 | Initial Entry |

5.c Result:

| Date   | Location        | User                       | Value                      | Reason        |
|--|-----------------|----------------------------|----------------------------|---------------|
| Dec-03-2020 10:15:40<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>36.3 | Initial Entry |

5.c LNMT

| Date   | Location        | User                       | Value  | Reason        |
|--|-----------------|----------------------------|--|---------------|
| Dec-03-2020 10:15:40<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br><br><i>Low</i><br>0<br><br><i>High</i><br>50<br><br><i>Unit</i><br>U/L | Initial Entry |

5.d

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Dec-03-2020 10:15:40<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Alkaline Phosphatase_PX35<br><b>Result::</b> 74<br><b>Not Done::</b> | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Lab Normal Range:</b><br><i>Low</i><br>30<br><br><i>High</i><br>120<br><br><i>Unit</i><br>U/L |  |
|--|--|--|--|--|

5.d Sponsor ID:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Dec-03-2020 10:15:40<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>35 | Initial Entry |

5.d Test:

| Date   | Location        | User                       | Value   | Reason        |
|--|-----------------|----------------------------|---|---------------|
| Dec-03-2020 10:15:40<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Alkaline Phosphatase_PX35 | Initial Entry |

5.d Result:

| Date   | Location        | User                       | Value                    | Reason        |
|--|-----------------|----------------------------|--------------------------|---------------|
| Dec-03-2020 10:15:40<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>74 | Initial Entry |

5.d LNMT

| Date   | Location        | User                       | Value  | Reason        |
|--|-----------------|----------------------------|--|---------------|
| Dec-03-2020 10:15:40<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br><i>Low</i><br>30<br><br><i>High</i><br>120<br><br><i>Unit</i><br>U/L | Initial Entry |

5.e

| Date   | Location        | User                    | Value              | Reason        |
|--|-----------------|-------------------------|--------------------|---------------|
| Dec-03-2020 10:15:40<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b> | Initial Entry |

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Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | <b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Bilirubin_PX 21<br><b>Result::</b> 0.43<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 0.3<br><br><i>High</i> 1.2<br><br><i>Unit</i> mg/dL |  |
|--|--|--|---|--|

5.e Sponsor ID:

| Date                                      | Location        | User                 | Value                 | Reason        |
|---|-----------------|----------------------|-----------------------|---------------|
| Dec-03-2020 10:15:40 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b> 21 | Initial Entry |

5.e Test:

| Date                                      | Location        | User                    | Value                             | Reason        |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Dec-03-2020 10:15:40 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b> Bilirubin_PX21 | Initial Entry |

5.e Result:

| Date                                      | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Dec-03-2020 10:15:40 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b> 0.43 | Initial Entry |

5.e LNMT

| Date                                      | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Dec-03-2020 10:15:40 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b><br><i>Low</i> 0.3<br><br><i>High</i> 1.2<br><br><i>Unit</i> mg/dL | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

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**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

5.f

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Dec-03-2020 10:15:40<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Blood Urea Nitrogen_PX47<br><b>Result::</b> 19<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 7<br><br><i>High</i> 20<br><br><i>Unit</i><br>mg/dL | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.f Sponsor ID:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Dec-03-2020 10:15:40<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>47 | Initial Entry |

5.f Test:

| Date   | Location        | User                          | Value  | Reason        |
|--|-----------------|-------------------------------|--|---------------|
| Dec-03-2020 10:15:40<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Blood Urea Nitrogen_PX47 | Initial Entry |

5.f Result:

| Date   | Location        | User                          | Value                    | Reason        |
|--|-----------------|-------------------------------|--------------------------|---------------|
| Dec-03-2020 10:15:40<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>19 | Initial Entry |

5.f LNMT

| Date   | Location        | User                          | Value  | Reason        |
|--|-----------------|-------------------------------|--|---------------|
| Dec-03-2020 10:15:40<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><br><i>Low</i><br>7<br><br><i>High</i><br>20<br><br><i>Unit</i><br>mg/dL | Initial Entry |

5.g

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Dec-03-2020 10:15:40<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Creatinine_P<br>X48<br><b>Result::</b> 0.87<br><b>Not Done::</b> | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Lab Normal Range:</b> <i>Low</i><br>0.67<br><br><i>High</i><br>1.17<br><br><i>Unit</i><br>mg/dL |  |
|--|--|--|--|--|

5.g Sponsor ID:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Dec-03-2020 10:15:40<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>48 | Initial Entry |

5.g Test:

| Date   | Location        | User                          | Value                                 | Reason        |
|--|-----------------|-------------------------------|---------------------------------------|---------------|
| Dec-03-2020 10:15:40<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Creatinine_PX48 | Initial Entry |

5.g Result:

| Date   | Location        | User                          | Value                      | Reason        |
|--|-----------------|-------------------------------|----------------------------|---------------|
| Dec-03-2020 10:15:40<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>0.87 | Initial Entry |

5.g LNMT

| Date   | Location        | User                          | Value   | Reason        |
|--|-----------------|-------------------------------|---|---------------|
| Dec-03-2020 10:15:40<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><i>Low</i><br>0.67<br><br><i>High</i><br>1.17<br><br><i>Unit</i><br>mg/dL | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Audit Trail

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

**Form Status:**

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Date   | Location        | User                | Value        | Reason |
|--|-----------------|---------------------|--------------|--------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Form Created |        |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Audit Trail

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

**Form Status:**

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Date   | Location        | User                | Value        | Reason |
|--|-----------------|---------------------|--------------|--------|
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Form Created |        |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Audit Trail

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

**Form Status:**

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Date   | Location        | User                          | Value        | Reason |
|--|-----------------|-------------------------------|--------------|--------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Created |        |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Audit Trail

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

**Form Status:**

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Date   | Location        | User                          | Value        | Reason |
|--|-----------------|-------------------------------|--------------|--------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Created |        |



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Audit Trail

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

**Form Status:**

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Date   | Location        | User                          | Value        | Reason |
|--|-----------------|-------------------------------|--------------|--------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Created |        |

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form Version: 10-Oct-2020 16:02

Site No: 1217

Subject No: 12171044

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Lab Panel:**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>HEMATOLOGY | Initial Entry |

**2. Laboratory Name and Address**

| Date   | Location        | User                      | Value  | Reason  |
|--|-----------------|---------------------------|--|---|
| Dec-02-2020 19:05:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 2: Closed  | Data updated.   |
| Dec-02-2020 16:17:13<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 2: Answered  | Changed Information   |
| Dec-02-2020 16:17:13<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>Kocaeli Universitesi Arastirma ve Uygulama Hastanesi Merkez Laboratuvari, Umuttepe 41380 Kocaeli ,TURKEY                   | Changed Information   |
| Dec-02-2020 14:13:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 2: Opened  | DM RQ1 :A carriage return is still identified, Please click into the enterable page and press delete and backspace multiple times to remove the characters. Do not press enter key, just type lab name all in single line with comma separated. |
| Nov-17-2020 08:59:22<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Closed  | Response satisfies query  |
| Nov-16-2020 16:54:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Answered  | Transcription Error   |
| Nov-16-2020 16:54:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>Lab Name:Kocaeli Universitesi Arastirma ve Uygulama Hastanesi Merkez Laboratuvari, Address: Umuttepe 41380 Kocaeli ,TURKEY | Transcription Error   |
| Nov-15-2020 20:28:22<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Opened  | DM :A carriage return is identified, please do  |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1217**Subject No:** 12171044**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1217) Kocaeli University Faculty of Medicine**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:11

|  |                 |                     |   |  |
|--|-----------------|---------------------|---|--|
|  |                 | (b) (4), (b) (6)    |   | not press enter key, just type lab name all in single line with comma separated. |
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>adress: Lab Name:Kocaeli Universit<br>esi Arastirma ve Uygulama Hastanesi<br>i PCR Laboratuari<br>Name:Kocaeli Universitesi Arastirm<br>a ve Uygulama Hastanesi PCR | Initial Entry  |

**3. Collection Date:**

| Date   | Location        | User                      | Value                             | Reason   |
|--|-----------------|---------------------------|-----------------------------------|--|
| Nov-16-2020 12:08:55<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Closed                   | Close Auto Query   |
| Nov-16-2020 11:52:37<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Opened                   | Collection Date is before Date of First Symptom Started on the Signs and Symptoms form in the same visit. Please review and update as appropriate. |
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>Nov/10/2020 | Initial Entry  |

**4. Specimen Type:**

| Date   | Location        | User                    | Value                       | Reason        |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>BLOOD | Initial Entry |

**5.a**

| Date   | Location        | User                | Value   | Reason              |
|--|-----------------|---------------------|---|---------------------|
| Nov-17-2020 15:18:15<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sponsor-Defined Iden 1</b><br><b>tifier:</b><br><b>Test::</b> Hemoglobin_<br>PX1<br><b>Result::</b> 15.11<br><b>Not Done::</b> | Transcription Error |

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1217**Subject No:** 12171044**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1217) Kocaeli University Faculty of Medicine**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:11

|  |                 |                         |  |               |
|--|-----------------|-------------------------|--|---------------|
|  |                 |                         | <b>Lab Normal Range:</b> <i>Low</i><br>12.5<br><br><i>High</i><br>16.3<br><br><i>Unit</i><br>g/dL  |               |
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Hemoglobin_PX1<br><b>Result::</b> 15.11<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>12.5<br><br><i>High</i><br>16.3<br><br><i>Unit</i><br>10 <sup>3</sup> /uL | Initial Entry |

**5.a Sponsor ID:**

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>1 | Initial Entry |

**5.a Test:**

| Date   | Location        | User                              | Value                                | Reason        |
|--|-----------------|-----------------------------------|--------------------------------------|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)<br>[REDACTED] | <b>Data Entry:</b><br>Hemoglobin_PX1 | Initial Entry |

**5.a Result:**

| Date   | Location        | User                              | Value             | Reason                   |
|--|-----------------|-----------------------------------|-------------------|--------------------------|
| Nov-17-2020 18:38:17<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)<br>[REDACTED] | Query 1: Closed   | Response satisfies query |
| Nov-17-2020 15:21:10<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)<br>[REDACTED] | Query 1: Answered | updated                  |

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |                 |                     |                             |                                 |
|--|-----------------|---------------------|-----------------------------|---------------------------------|
| Nov-16-2020 20:34:26<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Opened             | please correct the unit to g/dL |
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>15.11 | Initial Entry                   |

5.a LNMT

| Date   | Location        | User                | Value   | Reason              |
|--|-----------------|---------------------|---|---------------------|
| Nov-17-2020 15:18:15<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><i>Low</i><br>12.5<br><br><i>High</i><br>16.3<br><br><i>Unit</i><br>g/dL    | Transcription Error |
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><i>Low</i><br>12.5<br><br><i>High</i><br>16.3<br><br><i>Unit</i><br>10^3/uL | Initial Entry       |

5.b

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Hematocrit_P X2<br><b>Result::</b> 43.32<br><b>Not Done::</b> | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Lab Normal Range:</b> <i>Low</i><br>36.7<br><br><i>High</i><br>47.1<br><br><i>Unit</i><br>% |  |
|--|--|--|--|--|

5.b Sponsor ID:

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>2 | Initial Entry |

5.b Test:

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Hematocrit_PX2 | Initial Entry |

5.b Result:

| Date   | Location        | User                | Value                       | Reason        |
|--|-----------------|---------------------|-----------------------------|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>43.32 | Initial Entry |

5.b LNMT

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><i>Low</i><br>36.7<br><br><i>High</i><br>47.1<br><br><i>Unit</i><br>% | Initial Entry |

5.c

| Date   | Location        | User                | Value              | Reason              |
|--|-----------------|---------------------|--------------------|---------------------|
| Nov-17-2020 15:20:52<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b> | Transcription Error |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

**Site No:** 1217

**Subject No:** 12171044

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

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

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

|   |                 |                      |   |               |
|---|-----------------|----------------------|---|---------------|
|   |                 | (b) (4), (b) (6)     | <b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Erythrocytes_PX3<br><b>Result::</b> 5.101<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 4.06<br><i>High</i> 5.63<br><br><i>Unit</i><br>10 <sup>12</sup> /L                            |               |
| Nov-13-2020 11:46:38 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 3<br><b>Test::</b> Erythrocytes_PX3<br><b>Result::</b> 5.101<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 4.06<br><i>High</i> 5.63<br><br><i>Unit</i><br>10 <sup>6</sup> /cu mm | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.c Sponsor ID:

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>3 | Initial Entry |

5.c Test:

| Date   | Location        | User                | Value                                  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Erythrocytes_PX3 | Initial Entry |

5.c Result:

| Date   | Location        | User                | Value                       | Reason        |
|--|-----------------|---------------------|-----------------------------|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>5.101 | Initial Entry |

5.c LNMT

| Date   | Location        | User                      | Value   | Reason                   |
|--|-----------------|---------------------------|---|--------------------------|
| Nov-17-2020 18:38:35<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Closed   | Response satisfies query |
| Nov-17-2020 15:20:52<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Answered   | Transcription Error      |
| Nov-17-2020 15:20:52<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br><i>Low</i><br>4.06<br><br><i>High</i><br>5.63<br><br><i>Unit</i><br>10^12/L | Transcription Error      |
| Nov-16-2020 20:36:32<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Opened   | please correct the unit  |
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br><i>Low</i><br>4.06<br><br><i>High</i>                                       | Initial Entry            |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |                                       |  |
|--|--|--|---------------------------------------|--|
|  |  |  | 5.63                                  |  |
|  |  |  | <i>Unit</i><br>10 <sup>6</sup> /cu mm |  |

5.d

| Date   | Location        | User                    | Value   | Reason              |
|--|-----------------|-------------------------|---|---------------------|
| Nov-17-2020 15:21:30<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Platelets_P X5<br><b>Result::</b> 240.9<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 152<br><br><i>High</i> 348<br><br><i>Unit</i> 10 <sup>3</sup> /uL | Transcription Error |
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Platelets_P X5<br><b>Result::</b> 240<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 152<br><br><i>High</i> 348<br><br><i>Unit</i> 10 <sup>3</sup> /uL   | Initial Entry       |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.d Sponsor ID:

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>5 | Initial Entry |

5.d Test:

| Date   | Location        | User                | Value                               | Reason        |
|--|-----------------|---------------------|-------------------------------------|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Platelets_PX5 | Initial Entry |

5.d Result:

| Date   | Location        | User                      | Value                       | Reason                    |
|--|-----------------|---------------------------|-----------------------------|---------------------------|
| Nov-17-2020 18:38:52<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Closed             | Response satisfies query  |
| Nov-17-2020 15:21:30<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Answered           | Transcription Error       |
| Nov-17-2020 15:21:30<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>240.9 | Transcription Error       |
| Nov-16-2020 20:37:22<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Opened             | please correct the result |
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>240   | Initial Entry             |

5.d LNMT

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Low<br>152<br><br>High<br>348<br><br>Unit<br>10^3/uL | Initial Entry |

5.e

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

| Date   | Location        | User                    | Value   | Reason              |
|--|-----------------|-------------------------|---|---------------------|
| Nov-17-2020 15:22:30<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Leukocytes_P X7<br><b>Result::</b> 8.658<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 3.6<br><br><i>High</i> 10.2<br><br><i>Unit</i> 10^3/uL | Transcription Error |
| Nov-17-2020 15:22:07<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Leukocytes_P X7<br><b>Result::</b> 8.658<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 3.6<br><br><i>High</i> 6.2<br><br><i>Unit</i> 10^3/uL  | Transcription Error |
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Leukocytes_P X7<br><b>Result::</b> 8.8658<br><b>Not Done::</b>  | Initial Entry       |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

|  |  |  |                          |                                    |  |
|--|--|--|--------------------------|------------------------------------|--|
|  |  |  | <b>Lab Normal Range:</b> | <i>Low</i><br>3.6                  |  |
|  |  |  |                          | <i>High</i><br>6.2                 |  |
|  |  |  |                          | <i>Unit</i><br>10 <sup>3</sup> /uL |  |

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.e Sponsor ID:

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>7 | Initial Entry |

5.e Test:

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>Leukocytes_PX7 | Initial Entry |

5.e Result:

| Date   | Location        | User                      | Value                        | Reason  |
|--|-----------------|---------------------------|------------------------------|---|
| Nov-17-2020 18:39:10<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Closed              | Response satisfies query                            |
| Nov-17-2020 15:22:07<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Answered            | Transcription Error                                 |
| Nov-17-2020 15:22:07<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <u>Data Entry:</u><br>8.658  | Transcription Error                                 |
| Nov-16-2020 20:41:33<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Opened              | please review and correct all lab results and units |
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <u>Data Entry:</u><br>8.8658 | Initial Entry                                       |

5.e LNMT

| Date   | Location        | User                | Value   | Reason              |
|--|-----------------|---------------------|---|---------------------|
| Nov-17-2020 15:22:30<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>Low<br>3.6<br><br>High<br>10.2<br><br>Unit<br>10^3/uL | Transcription Error |
| Nov-13-2020 11:46:38                         | ACV0PFEINFP6000 | (b) (4), (b) (6)    | <u>Data Entry:</u>  | Initial Entry       |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|                      |                     |            |             |                 |
|----------------------|---------------------|------------|-------------|-----------------|
| (UTC+03:00) Istanbul | (b) (4),<br>(b) (6) | Low<br>3.6 | High<br>6.2 | Unit<br>10^3/uL |
|----------------------|---------------------|------------|-------------|-----------------|

5.f

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 608<br><b>Test::</b> Neutrophils_P<br>X608<br><b>Result::</b> 6.836<br><b>Not Done::</b><br><b>Lab Normal Range:</b> Low<br>1.7<br>High<br>7.6<br>Unit<br>10^3/uL | Initial Entry |

5.f Sponsor ID:

| Date   | Location        | User                    | Value                     | Reason        |
|--|-----------------|-------------------------|---------------------------|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>608 | Initial Entry |

5.f Test:

| Date   | Location        | User                | Value                                   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Neutrophils_PX608 | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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5.f Result:

| Date   | Location        | User                | Value                       | Reason        |
|--|-----------------|---------------------|-----------------------------|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>6.836 | Initial Entry |

5.f LNMT

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><i>Low</i><br>1.7<br><i>High</i><br>7.6<br><i>Unit</i><br>10 <sup>3</sup> /uL | Initial Entry |

5.g

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 609<br><b>Test::</b> Eosinophils_P X609<br><b>Result::</b> 0.095<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>0<br><i>High</i><br>0.5<br><i>Unit</i><br>10 <sup>3</sup> /uL | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.g Sponsor ID:

| Date   | Location        | User                    | Value                     | Reason        |
|--|-----------------|-------------------------|---------------------------|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>609 | Initial Entry |

5.g Test:

| Date   | Location        | User                | Value                                   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Eosinophils_PX609 | Initial Entry |

5.g Result:

| Date   | Location        | User                | Value                       | Reason        |
|--|-----------------|---------------------|-----------------------------|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>0.095 | Initial Entry |

5.g LNMT

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><i>Low</i><br>0<br><br><i>High</i><br>0.5<br><br><i>Unit</i><br>10 <sup>3</sup> /uL | Initial Entry |

5.h

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 612<br><b>Test::</b> Monocytes_PX<br>612<br><b>Result::</b> 0.871<br><b>Not Done::</b> | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Lab Normal Range:</b> <i>Low</i><br>0.3<br><br><i>High</i><br>1.1<br><br><i>Unit</i><br>10^3/uL |  |
|--|--|--|--|--|

5.h Sponsor ID:

| Date   | Location        | User                    | Value                     | Reason        |
|--|-----------------|-------------------------|---------------------------|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>612 | Initial Entry |

5.h Test:

| Date   | Location        | User                | Value                                 | Reason        |
|--|-----------------|---------------------|---------------------------------------|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Monocytes_PX612 | Initial Entry |

5.h Result:

| Date   | Location        | User                | Value                       | Reason        |
|--|-----------------|---------------------|-----------------------------|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>0.871 | Initial Entry |

5.h LNMT

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><i>Low</i><br>0.3<br><br><i>High</i><br>1.1<br><br><i>Unit</i><br>10^3/uL | Initial Entry |

5.i

| Date   | Location        | User                | Value              | Reason              |
|--|-----------------|---------------------|--------------------|---------------------|
| Nov-17-2020 15:24:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b> | Transcription Error |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form Version: 10-Oct-2020 16:02

Site No: 1217

Subject No: 12171044

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

|  |                 |                         |   |               |
|--|-----------------|-------------------------|---|---------------|
|  |                 | (b) (4), (b) (6)        | <b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Basophils_PX 610<br><b>Result::</b> 0.027<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>0<br><br><i>High</i><br>0.1<br><br><i>Unit</i><br>10 <sup>3</sup> /uL                        |               |
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Basophils_PX 610<br><b>Result::</b> 0.027<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>0<br><br><i>High</i><br>0.01<br><br><i>Unit</i><br>10 <sup>3</sup> /uL | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.i Sponsor ID:

| Date   | Location        | User                    | Value                     | Reason        |
|--|-----------------|-------------------------|---------------------------|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>610 | Initial Entry |

5.i Test:

| Date   | Location        | User                | Value                                 | Reason        |
|--|-----------------|---------------------|---------------------------------------|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>Basophils_PX610 | Initial Entry |

5.i Result:

| Date   | Location        | User                | Value                       | Reason        |
|--|-----------------|---------------------|-----------------------------|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>0.027 | Initial Entry |

5.i LNMT

| Date   | Location        | User                | Value   | Reason              |
|--|-----------------|---------------------|---|---------------------|
| Nov-17-2020 15:24:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>Low<br>0<br><br>High<br>0.1<br><br>Unit<br>10^3/uL  | Transcription Error |
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>Low<br>0<br><br>High<br>0.01<br><br>Unit<br>10^3/uL | Initial Entry       |

5.j

| Date   | Location        | User                    | Value              | Reason        |
|--|-----------------|-------------------------|--------------------|---------------|
| Nov-13-2020 11:46:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u> | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | <b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Lymphocytes_PX611<br><b>Result::</b> 0.830<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>1<br><br><i>High</i><br>3.2<br><br><i>Unit</i><br>10^3/uL |  |
|--|--|--|---|--|

**5.j Sponsor ID:**

| Date                                      | Location        | User                 | Value                     | Reason        |
|---|-----------------|----------------------|---------------------------|---------------|
| Nov-13-2020 11:46:38 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br>611 | Initial Entry |

**5.j Test:**

| Date                                      | Location        | User                | Value                                   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Nov-13-2020 11:46:38 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Lymphocytes_PX611 | Initial Entry |

**5.j Result:**

| Date                                      | Location        | User                | Value                       | Reason        |
|---|-----------------|---------------------|-----------------------------|---------------|
| Nov-13-2020 11:46:38 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>0.830 | Initial Entry |

**5.j LNMT**

| Date                                      | Location        | User                | Value   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Nov-13-2020 11:46:38 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><i>Low</i><br>1<br><br><i>High</i><br>3.2<br><br><i>Unit</i><br>10^3/uL | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1217**Subject No:** 12171044**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1217) Kocaeli University Faculty of Medicine**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Lab Panel:**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>HEMATOLOGY | Initial Entry |

**2. Laboratory Name and Address**

| Date   | Location        | User                       | Value   | Reason   |
|--|-----------------|----------------------------|---|--|
| Dec-03-2020 12:30:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Balaji Prabu R<br>(b) (4)  | Query 1: Closed   | Response satisfies query   |
| Dec-03-2020 08:59:37<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | Query 1: Answered   | For all results and ranges below, the comma has been replaced with a decimal number.   |
| Dec-03-2020 02:41:11<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Erica Weaver<br>(b) (4)    | Query 1: Opened   | FOR all the results below and ranges, Please replace the comma with a decimal. Thanks. |
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br>Lab Name:Kocaeli Universitesi Arastirma ve Uygulama Hastanesi Merkez Laboratuvari, Address: Umuttepe 413 80 Kocaeli ,TURKEY | Initial Entry  |

**3. Collection Date:**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/16/2020 | Initial Entry |

**4. Specimen Type:**

| Date   | Location        | User                    | Value                       | Reason        |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>BLOOD | Initial Entry |

**5.a**

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

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form Version: 10-Oct-2020 16:02

Site No: 1217

Subject No: 12171044

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

|  |                 |                               |  |                     |
|--|-----------------|-------------------------------|--|---------------------|
| Dec-03-2020 08:50:14<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Hemoglobin_PX1<br><b>Result::</b> 16.17<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 12.5<br><i>High</i> 16.3<br><i>Unit</i> g/dL | Changed Information |
| Dec-03-2020 08:49:20<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Hemoglobin_PX1<br><b>Result::</b> 16.17<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 12,5<br><i>High</i> 16,3<br><i>Unit</i> g/dL | Changed Information |
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc)       | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Hemoglobin_PX1<br><b>Result::</b> 16,17<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 12,5<br><i>High</i> 16,3<br><i>Unit</i> g/dL | Initial Entry       |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.a Sponsor ID:

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>1 | Initial Entry |

5.a Test:

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Hemoglobin_PX1 | Initial Entry |

5.a Result:

| Date   | Location        | User                          | Value                       | Reason              |
|--|-----------------|-------------------------------|-----------------------------|---------------------|
| Dec-03-2020 08:49:20<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>16.17 | Changed Information |
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b><br>16,17 | Initial Entry       |

5.a LNMT

| Date   | Location        | User                          | Value  | Reason              |
|--|-----------------|-------------------------------|--|---------------------|
| Dec-03-2020 08:50:14<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><i>Low</i><br>12.5<br><i>High</i><br>16.3<br><i>Unit</i><br>g/dL | Changed Information |
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b><br><i>Low</i><br>12,5<br><i>High</i><br>16,3<br><i>Unit</i><br>g/dL | Initial Entry       |

5.b

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

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1217**Subject No:** 12171044**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1217) Kocaeli University Faculty of Medicine**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:11

|  |                 |                               |  |                     |
|--|-----------------|-------------------------------|--|---------------------|
| Dec-03-2020 08:50:33<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 2<br><b>Test::</b> Hematocrit_PX2<br><b>Result::</b> 45.27<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 36.7<br><i>High</i> 47.1<br><br><i>Unit</i><br>% | Changed Information |
| Dec-03-2020 08:49:37<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 2<br><b>Test::</b> Hematocrit_PX2<br><b>Result::</b> 45.27<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 36,7<br><i>High</i> 47,1<br><br><i>Unit</i><br>% | Changed Information |
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc)       | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 2<br><b>Test::</b> Hematocrit_PX2<br><b>Result::</b> 45,27<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 36,7<br><i>High</i> 47,1<br><br><i>Unit</i><br>% | Initial Entry       |



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.b Sponsor ID:

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>2 | Initial Entry |

5.b Test:

| Date   | Location        | User                | Value                                | Reason        |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Hematocrit_PX2 | Initial Entry |

5.b Result:

| Date   | Location        | User                          | Value                       | Reason              |
|--|-----------------|-------------------------------|-----------------------------|---------------------|
| Dec-03-2020 08:49:37<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>45.27 | Changed Information |
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b><br>45,27 | Initial Entry       |

5.b LNMT

| Date   | Location        | User                          | Value   | Reason              |
|--|-----------------|-------------------------------|---|---------------------|
| Dec-03-2020 08:50:33<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><i>Low</i><br>36.7<br><i>High</i><br>47.1<br><i>Unit</i><br>% | Changed Information |
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b><br><i>Low</i><br>36,7<br><i>High</i><br>47,1<br><i>Unit</i><br>% | Initial Entry       |

5.c

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

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |                 |                            |   |                     |
|--|-----------------|----------------------------|---|---------------------|
| Dec-03-2020 08:50:55<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 3<br><b>Test::</b> Erythrocytes_PX3<br><b>Result::</b> 5.355<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 4.06<br><br><i>High</i> 5.63<br><br><i>Unit</i> 10^12/L | Changed Information |
| Dec-03-2020 08:49:49<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 3<br><b>Test::</b> Erythrocytes_PX3<br><b>Result::</b> 5.355<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 4,06<br><br><i>High</i> 5,63<br><br><i>Unit</i> 10^12/L | Changed Information |
| Nov-17-2020 16:56:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 3<br><b>Test::</b> Erythrocytes_PX3<br><b>Result::</b> 5,355<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 4,06<br><br><i>High</i> 5,63<br><br><i>Unit</i> 10^12/L | Transcription Error |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

**Site No:** 1217

**Subject No:** 12171044

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

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

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

|  |                 |                         |  |               |
|--|-----------------|-------------------------|--|---------------|
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Erythrocytes_PX3<br><b>Result::</b> 5,355<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>4,06<br><br><i>High</i><br>5,63 | Initial Entry |
|--|-----------------|-------------------------|--|---------------|

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.c Sponsor ID:

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>3 | Initial Entry |

5.c Test:

| Date   | Location        | User                | Value                                  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Erythrocytes_PX3 | Initial Entry |

5.c Result:

| Date   | Location        | User                          | Value                       | Reason   |
|--|-----------------|-------------------------------|-----------------------------|--|
| Dec-03-2020 08:49:49<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>5.355 | Changed Information  |
| Nov-17-2020 16:56:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)     | Query 1: Closed             | Close Auto Query   |
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)     | Query 1: Opened             | Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm. |
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b><br>5,355 | Initial Entry  |

5.c LNMT

| Date   | Location        | User                          | Value   | Reason              |
|--|-----------------|-------------------------------|---|---------------------|
| Dec-03-2020 08:50:55<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><i>Low</i><br>4.06<br><br><i>High</i><br>5.63<br><br><i>Unit</i><br>10^12/L | Changed Information |
| Nov-17-2020 16:56:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b><br><i>Low</i><br>4,06  | Transcription Error |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |                 |                     |   |               |
|--|-----------------|---------------------|---|---------------|
|  |                 |                     | High<br>5,63  |               |
|  |                 |                     | Unit<br>10^12/L                                       |               |
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Low<br>4,06<br><br>High<br>5,63 | Initial Entry |

5.d

| Date   | Location        | User                          | Value  | Reason              |
|--|-----------------|-------------------------------|--|---------------------|
| Dec-03-2020 08:51:55<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Platelets_P<br>X5<br><b>Result::</b> 200.6<br><b>Not Done::</b><br><b>Lab Normal Range:</b> Low<br>152<br><br>High<br>348<br><br>Unit<br>10^3/uL | Changed Information |
| Nov-17-2020 16:57:02<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Platelets_P<br>X5<br><b>Result::</b> 200,6<br><b>Not Done::</b><br><b>Lab Normal Range:</b> Low<br>152<br><br>High<br>348<br><br>Unit<br>10^3/uL | Transcription Error |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

**Site No:** 1217

**Subject No:** 12171044

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

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

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

|  |                 |                         |   |               |
|--|-----------------|-------------------------|---|---------------|
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Platelets_P<br>X5<br><b>Result::</b> 200,6<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>152<br><br><i>High</i><br>348 | Initial Entry |
|--|-----------------|-------------------------|---|---------------|

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.d Sponsor ID:

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>5 | Initial Entry |

5.d Test:

| Date   | Location        | User                | Value                               | Reason        |
|--|-----------------|---------------------|-------------------------------------|---------------|
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Platelets_PX5 | Initial Entry |

5.d Result:

| Date   | Location        | User                          | Value                       | Reason   |
|--|-----------------|-------------------------------|-----------------------------|--|
| Dec-03-2020 08:51:55<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>200.6 | Changed Information  |
| Nov-17-2020 16:57:02<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)     | Query 1: Closed             | Close Auto Query   |
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)     | Query 1: Opened             | Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm. |
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b><br>200,6 | Initial Entry  |

5.d LNMT

| Date   | Location        | User                | Value   | Reason              |
|--|-----------------|---------------------|---|---------------------|
| Nov-17-2020 16:57:02<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><i>Low</i><br>152<br><br><i>High</i><br>348<br><br><i>Unit</i><br>10^3/uL | Transcription Error |
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><i>Low</i><br>152   | Initial Entry       |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |             |  |
|--|--|--|-------------|--|
|  |  |  | High<br>348 |  |
|--|--|--|-------------|--|

5.e

| Date   | Location        | User                       | Value  | Reason              |
|--|-----------------|----------------------------|--|---------------------|
| Dec-03-2020 08:52:46<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 7<br><b>Test::</b> Leukocytes_PX7<br><b>Result::</b> 7.115<br><b>Not Done::</b><br><b>Lab Normal Range:</b> Low<br>3.6<br><br>High<br>10.2<br><br>Unit<br>10^3/uL | Changed Information |
| Dec-03-2020 08:52:20<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 7<br><b>Test::</b> Leukocytes_PX7<br><b>Result::</b> 7.115<br><b>Not Done::</b><br><b>Lab Normal Range:</b> Low<br>3,6<br><br>High<br>10,2<br><br>Unit<br>10^3/uL | Changed Information |
| Nov-17-2020 16:57:35<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 7<br><b>Test::</b> Leukocytes_PX7<br><b>Result::</b> 7,115<br><b>Not Done::</b>   | Transcription Error |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|   |                 |                      |   |               |
|---|-----------------|----------------------|---|---------------|
|   |                 |                      | <b>Lab Normal Range:</b> <i>Low</i><br>3,6<br><br><i>High</i><br>10,2<br><br><i>Unit</i><br>10^3/uL   |               |
| Nov-17-2020 16:37:34 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 7<br><b>Test::</b> Leukocytes_PX7<br><b>Result::</b> 7,115<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>3,6<br><br><i>High</i><br>10,2 | Initial Entry |

5.e Sponsor ID:

| Date                                      | Location        | User                 | Value                   | Reason        |
|---|-----------------|----------------------|-------------------------|---------------|
| Nov-17-2020 16:37:34 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br>7 | Initial Entry |

5.e Test:

| Date                                      | Location        | User                              | Value                                | Reason        |
|---|-----------------|-----------------------------------|--------------------------------------|---------------|
| Nov-17-2020 16:37:34 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)<br>[Redacted] | <b>Data Entry:</b><br>Leukocytes_PX7 | Initial Entry |

5.e Result:

| Date                                      | Location        | User                       | Value                       | Reason              |
|---|-----------------|----------------------------|-----------------------------|---------------------|
| Dec-03-2020 08:52:20 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>7.115 | Changed Information |
| Nov-17-2020 16:57:35 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query (autoquery)     | Query 1: Closed             | Close Auto Query    |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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5.e Result:

| Date                                      | Location        | User                   | Value                       | Reason   |
|---|-----------------|------------------------|-----------------------------|--|
| Nov-17-2020 16:37:34 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened             | Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm. |
| Nov-17-2020 16:37:34 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)       | <b>Data Entry:</b><br>7,115 | Initial Entry  |

5.e LNMT

| Date                                      | Location        | User                    | Value  | Reason              |
|---|-----------------|-------------------------|--|---------------------|
| Dec-03-2020 08:52:46 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b><br><i>Low</i><br>3.6<br><i>High</i><br>10.2<br><i>Unit</i><br>10 <sup>3</sup> /uL | Changed Information |
| Nov-17-2020 16:57:35 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)        | <b>Data Entry:</b><br><i>Low</i><br>3,6<br><i>High</i><br>10,2<br><i>Unit</i><br>10 <sup>3</sup> /uL | Transcription Error |
| Nov-17-2020 16:37:34 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)        | <b>Data Entry:</b><br><i>Low</i><br>3,6<br><i>High</i><br>10,2                                       | Initial Entry       |

5.f

| Date                 | Location        | User   | Value              | Reason              |
|----------------------|-----------------|--------|--------------------|---------------------|
| Dec-03-2020 08:53:28 | ACV0PFEINFP6000 | Binnur | <b>Data Entry:</b> | Changed Information |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form Version: 10-Oct-2020 16:02

Site No: 1217

Subject No: 12171044

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

|  |                 |                               |   |                     |
|--|-----------------|-------------------------------|---|---------------------|
| (UTC+03:00) Istanbul                         |                 | Yildirim<br>(b) (4)           | <b>Sponsor-Defined Identifier:</b> 608<br><b>Test::</b> Neutrophils_P X608<br><b>Result::</b> 5.596<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 1.7<br><br><i>High</i> 7.6<br><br><i>Unit</i> 10^3/uL                       |                     |
| Dec-03-2020 08:53:07<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 608<br><b>Test::</b> Neutrophils_P X608<br><b>Result::</b> 5.596<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 1,7<br><br><i>High</i> 7,6<br><br><i>Unit</i> 10^3/uL | Changed Information |
| Nov-17-2020 16:58:56<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 608<br><b>Test::</b> Neutrophils_P X608<br><b>Result::</b> 5,596<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 1,7<br><br><i>High</i> 7,6<br><br><i>Unit</i> 10^3/uL | Changed Information |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

**Site No:** 1217

**Subject No:** 12171044

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

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

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

|  |                 |                         |  |                     |
|--|-----------------|-------------------------|--|---------------------|
| Nov-17-2020 16:58:25<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 608<br><b>Test::</b> Neutrophils_P<br>X608<br><b>Result::</b> 5,596<br><b>Not Done::</b><br><b>Lab Normal Range</b> <i>Low</i><br>: 43,5<br><br><i>High</i><br>73,5<br><br><i>Unit</i><br>% | Transcription Error |
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 608<br><b>Test::</b> Neutrophils_P<br>X608<br><b>Result::</b> 78,65<br><b>Not Done::</b><br><b>Lab Normal Range</b> <i>Low</i><br>: 43,5<br><br><i>High</i><br>73,5<br><br><i>Unit</i><br>% | Initial Entry       |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.f Sponsor ID:

| Date   | Location        | User                    | Value                     | Reason        |
|--|-----------------|-------------------------|---------------------------|---------------|
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>608 | Initial Entry |

5.f Test:

| Date   | Location        | User                | Value                                   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Neutrophils_PX608 | Initial Entry |

5.f Result:

| Date   | Location        | User                          | Value                       | Reason              |
|--|-----------------|-------------------------------|-----------------------------|---------------------|
| Dec-03-2020 08:53:07<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>5.596 | Changed Information |
| Nov-17-2020 16:58:25<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b><br>5,596 | Transcription Error |
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b><br>78,65 | Initial Entry       |

5.f LNMT

| Date   | Location        | User                          | Value   | Reason              |
|--|-----------------|-------------------------------|---|---------------------|
| Dec-03-2020 08:53:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><i>Low</i><br>1.7<br><br><i>High</i><br>7.6<br><br><i>Unit</i><br>10 <sup>3</sup> /uL | Changed Information |
| Nov-17-2020 16:58:56<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b><br><i>Low</i><br>1,7<br><br><i>High</i><br>7,6<br><br><i>Unit</i><br>10 <sup>3</sup> /uL | Changed Information |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |                 |                     |   |               |
|--|-----------------|---------------------|---|---------------|
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><i>Low</i><br>43,5<br><br><i>High</i><br>73,5<br><br><i>Unit</i><br>% | Initial Entry |
|--|-----------------|---------------------|---|---------------|

5.g

| Date   | Location        | User                       | Value  | Reason              |
|--|-----------------|----------------------------|--|---------------------|
| Dec-03-2020 08:54:10<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br><b>Sponsor-Defined Id</b> 609<br><b>entifier:</b><br><b>Test::</b> Eosinophils_P<br>X609<br><b>Result::</b> 0.000<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>0<br><br><i>High</i><br>0.5<br><br><i>Unit</i><br>10^3/uL | Changed Information |
| Dec-03-2020 08:53:47<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br><b>Sponsor-Defined Id</b> 609<br><b>entifier:</b><br><b>Test::</b> Eosinophils_P<br>X609<br><b>Result::</b> 0.000<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>0<br><br><i>High</i><br>0,5<br><br><i>Unit</i><br>10^3/uL | Changed Information |
| Nov-17-2020 16:59:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br><b>Sponsor-Defined Id</b> 609<br><b>entifier:</b>  | Changed Information |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |                 |                         |  |                     |
|--|-----------------|-------------------------|--|---------------------|
|  |                 |                         | <b>Test::</b> Eosinophils_P<br>X609<br><b>Result::</b> 0,000<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>0<br><br><i>High</i><br>0,5<br><br><i>Unit</i><br>10^3/uL  |                     |
| Nov-17-2020 16:59:20<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 609<br><b>Test::</b> Eosinophils_P<br>X609<br><b>Result::</b> 0,000<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>:<br>0,8<br><br><i>High</i><br>8,1<br><br><i>Unit</i><br>% | Transcription Error |
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 609<br><b>Test::</b> Eosinophils_P<br>X609<br><b>Result::</b> 0,00<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>:<br>0,8<br><br><i>High</i><br>8,1<br><br><i>Unit</i><br>%  | Initial Entry       |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.g Sponsor ID:

| Date   | Location        | User                    | Value                     | Reason        |
|--|-----------------|-------------------------|---------------------------|---------------|
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>609 | Initial Entry |

5.g Test:

| Date   | Location        | User                | Value                                   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>Eosinophils_PX609 | Initial Entry |

5.g Result:

| Date   | Location        | User                          | Value                       | Reason              |
|--|-----------------|-------------------------------|-----------------------------|---------------------|
| Dec-03-2020 08:53:47<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <u>Data Entry:</u><br>0.000 | Changed Information |
| Nov-17-2020 16:59:20<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <u>Data Entry:</u><br>0,000 | Transcription Error |
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <u>Data Entry:</u><br>0,00  | Initial Entry       |

5.g LNMT

| Date   | Location        | User                          | Value   | Reason              |
|--|-----------------|-------------------------------|---|---------------------|
| Dec-03-2020 08:54:10<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <u>Data Entry:</u><br><i>Low</i><br>0<br><br><i>High</i><br>0.5<br><br><i>Unit</i><br>10^3/uL | Changed Information |
| Nov-17-2020 16:59:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <u>Data Entry:</u><br><i>Low</i><br>0<br><br><i>High</i><br>0,5<br><br><i>Unit</i><br>10^3/uL | Changed Information |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |                 |                     |   |               |
|--|-----------------|---------------------|---|---------------|
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><i>Low</i><br>0,8<br><br><i>High</i><br>8,1<br><br><i>Unit</i><br>% | Initial Entry |
|--|-----------------|---------------------|---|---------------|

5.h

| Date   | Location        | User                       | Value  | Reason              |
|--|-----------------|----------------------------|--|---------------------|
| Dec-03-2020 08:54:54<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br><b>Sponsor-Defined Id</b> 612<br><b>entifier:</b><br><b>Test::</b> Monocytes_P<br>X612<br><b>Result::</b> 0.386<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>0.3<br><br><i>High</i><br>1.1<br><br><i>Unit</i><br>10^3/uL | Changed Information |
| Dec-03-2020 08:54:31<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br><b>Sponsor-Defined Id</b> 612<br><b>entifier:</b><br><b>Test::</b> Monocytes_P<br>X612<br><b>Result::</b> 0.386<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>0,3<br><br><i>High</i><br>1,1<br><br><i>Unit</i><br>10^3/uL | Changed Information |
| Nov-17-2020 17:00:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br><b>Sponsor-Defined Id</b> 612<br><b>entifier:</b>  | Changed Information |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |                 |                         |  |                     |
|--|-----------------|-------------------------|--|---------------------|
|  |                 |                         | <b>Test::</b> Monocytes_P<br>X612<br><b>Result::</b> 0,386<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>0,3<br><br><i>High</i><br>1,1<br><br><i>Unit</i><br>10^3/uL  |                     |
| Nov-17-2020 17:00:20<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 612<br><b>Test::</b> Monocytes_P<br>X612<br><b>Result::</b> 0,386<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>5,5<br><br><i>High</i><br>13,7<br><br><i>Unit</i><br>% | Transcription Error |
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 612<br><b>Test::</b> Monocytes_P<br>X612<br><b>Result::</b> 5,42<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>5,5<br><br><i>High</i><br>13,7<br><br><i>Unit</i><br>%  | Initial Entry       |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.h Sponsor ID:

| Date   | Location        | User                    | Value                     | Reason        |
|--|-----------------|-------------------------|---------------------------|---------------|
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>612 | Initial Entry |

5.h Test:

| Date   | Location        | User                | Value                                 | Reason        |
|--|-----------------|---------------------|---------------------------------------|---------------|
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Monocytes_PX612 | Initial Entry |

5.h Result:

| Date   | Location        | User                          | Value                       | Reason              |
|--|-----------------|-------------------------------|-----------------------------|---------------------|
| Dec-03-2020 08:54:31<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>0.386 | Changed Information |
| Nov-17-2020 17:00:20<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b><br>0,386 | Transcription Error |
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b><br>5,42  | Initial Entry       |

5.h LNMT

| Date   | Location        | User                          | Value   | Reason              |
|--|-----------------|-------------------------------|---|---------------------|
| Dec-03-2020 08:54:54<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><i>Low</i><br>0.3<br><br><i>High</i><br>1.1<br><br><i>Unit</i><br>10^3/uL | Changed Information |
| Nov-17-2020 17:00:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b><br><i>Low</i><br>0,3<br><br><i>High</i><br>1,1<br><br><i>Unit</i><br>10^3/uL | Changed Information |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |                 |                     |  |               |
|--|-----------------|---------------------|--|---------------|
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><i>Low</i><br>5,5<br><br><i>High</i><br>13,7<br><br><i>Unit</i><br>% | Initial Entry |
|--|-----------------|---------------------|--|---------------|

5.i

| Date   | Location        | User                       | Value  | Reason              |
|--|-----------------|----------------------------|--|---------------------|
| Dec-03-2020 08:55:37<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 610<br><b>Test::</b> Basophils_P X610<br><b>Result::</b> 0.015<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>0<br><br><i>High</i><br>0.1<br><br><i>Unit</i><br>10 <sup>3</sup> /uL | Changed Information |
| Dec-03-2020 08:55:17<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 610<br><b>Test::</b> Basophils_P X610<br><b>Result::</b> 0.015<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>0<br><br><i>High</i><br>0,1<br><br><i>Unit</i><br>10 <sup>3</sup> /uL | Changed Information |
| Nov-17-2020 17:01:14<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 610   | Changed Information |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |                 |                         |   |                     |
|--|-----------------|-------------------------|---|---------------------|
|  |                 |                         | <b>Test::</b> Basophils_P<br>X610<br><b>Result::</b> 0,015<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>0<br><br><i>High</i><br>0,1<br><br><i>Unit</i><br>10^3/uL   |                     |
| Nov-17-2020 17:00:55<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 610<br><b>Test::</b> Basophils_P<br>X610<br><b>Result::</b> 0,015<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>0,2<br><br><i>High</i><br>1,5<br><br><i>Unit</i><br>% | Transcription Error |
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 610<br><b>Test::</b> Basophils_P<br>X610<br><b>Result::</b> 0,21<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>0,2<br><br><i>High</i><br>1,5<br><br><i>Unit</i><br>%  | Initial Entry       |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**5.i Sponsor ID:**

| Date   | Location        | User                    | Value                     | Reason        |
|--|-----------------|-------------------------|---------------------------|---------------|
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>610 | Initial Entry |

**5.i Test:**

| Date   | Location        | User                | Value                                 | Reason        |
|--|-----------------|---------------------|---------------------------------------|---------------|
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Basophils_PX610 | Initial Entry |

**5.i Result:**

| Date   | Location        | User                       | Value                       | Reason              |
|--|-----------------|----------------------------|-----------------------------|---------------------|
| Dec-03-2020 08:55:17<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>0.015 | Changed Information |
| Nov-17-2020 17:00:55<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br>0,015 | Transcription Error |
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br>0,21  | Initial Entry       |

**5.i LNMT**

| Date   | Location        | User                       | Value   | Reason              |
|--|-----------------|----------------------------|---|---------------------|
| Dec-03-2020 08:55:37<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br><i>Low</i><br>0<br><i>High</i><br>0.1<br><i>Unit</i><br>10 <sup>3</sup> /uL | Changed Information |
| Nov-17-2020 17:01:14<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br><i>Low</i><br>0<br><i>High</i><br>0,1<br><i>Unit</i>                        | Changed Information |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |                 |                     |   |               |
|--|-----------------|---------------------|---|---------------|
|  |                 |                     | 10 <sup>3</sup> /uL   |               |
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><i>Low</i><br>0,2<br><br><i>High</i><br>1,5<br><br><i>Unit</i><br>% | Initial Entry |

5.j

| Date   | Location        | User                       | Value  | Reason              |
|--|-----------------|----------------------------|--|---------------------|
| Dec-03-2020 08:56:12<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br><b>Sponsor-Defined Id 611</b><br><b>entifier:</b><br><b>Test::</b> Lymphocytes_<br>PX611<br><b>Result::</b> 1.118<br><b>Not Done::</b><br><b>Lab Normal Range</b> <i>Low</i><br>:<br>1<br><br><i>High</i><br>3.2<br><br><i>Unit</i><br>10 <sup>3</sup> /uL | Changed Information |
| Dec-03-2020 08:55:53<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br><b>Sponsor-Defined Id 611</b><br><b>entifier:</b><br><b>Test::</b> Lymphocytes_<br>PX611<br><b>Result::</b> 1.118<br><b>Not Done::</b><br><b>Lab Normal Range</b> <i>Low</i><br>:<br>1<br><br><i>High</i><br>3,2<br><br><i>Unit</i><br>10 <sup>3</sup> /uL | Changed Information |
| Nov-17-2020 17:01:52                         | ACV0PFEINFP6000 | (b) (4), (b) (6)           | <b>Data Entry:</b>   | Changed Information |

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |                 |                         |  |                     |
|--|-----------------|-------------------------|--|---------------------|
| (UTC+03:00) Istanbul                         |                 | (b) (4), (b) (6)        | <b>Sponsor-Defined Identifier:</b> 611<br><b>Test::</b> Lymphocytes_PX611<br><b>Result::</b> 1,118<br><b>Not Done::</b><br><b>Lab Normal Range</b> <i>Low</i><br>: 1<br><br><i>High</i><br>3,2<br><br><i>Unit</i><br>10^3/uL                     |                     |
| Nov-17-2020 17:01:30<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 611<br><b>Test::</b> Lymphocytes_PX611<br><b>Result::</b> 1,118<br><b>Not Done::</b><br><b>Lab Normal Range</b> <i>Low</i><br>: 15,2<br><br><i>High</i><br>43,3<br><br><i>Unit</i><br>% | Transcription Error |
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 611<br><b>Test::</b> Lymphocytes_PX611<br><b>Result::</b> 15,72<br><b>Not Done::</b><br><b>Lab Normal Range</b> <i>Low</i><br>: 15,2<br><br><i>High</i><br>43,3<br><br><i>Unit</i><br>% | Initial Entry       |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.j Sponsor ID:

| Date   | Location        | User                    | Value                     | Reason        |
|--|-----------------|-------------------------|---------------------------|---------------|
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>611 | Initial Entry |

5.j Test:

| Date   | Location        | User                | Value                                   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Lymphocytes_PX611 | Initial Entry |

5.j Result:

| Date   | Location        | User                          | Value                       | Reason              |
|--|-----------------|-------------------------------|-----------------------------|---------------------|
| Dec-03-2020 08:55:53<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>1.118 | Changed Information |
| Nov-17-2020 17:01:30<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b><br>1,118 | Transcription Error |
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b><br>15,72 | Initial Entry       |

5.j LNMT

| Date   | Location        | User                          | Value   | Reason              |
|--|-----------------|-------------------------------|---|---------------------|
| Dec-03-2020 08:56:12<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><i>Low</i><br>1<br><br><i>High</i><br>3.2<br><br><i>Unit</i><br>10^3/uL | Changed Information |
| Nov-17-2020 17:01:52<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b><br><i>Low</i><br>1<br><br><i>High</i><br>3,2<br><br><i>Unit</i><br>10^3/uL | Changed Information |

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

|  |                 |                     |   |               |
|--|-----------------|---------------------|---|---------------|
| Nov-17-2020 16:37:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><i>Low</i><br>15,2<br><br><i>High</i><br>43,3<br><br><i>Unit</i><br>% | Initial Entry |
|--|-----------------|---------------------|---|---------------|

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

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Generated By: (b) (4)

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1. Lab Panel:

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>HEMATOLOGY | Initial Entry |

2. Laboratory Name and Address

| Date   | Location        | User                          | Value   | Reason        |
|--|-----------------|-------------------------------|---|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Lab Name:Kocaeli Universitesi Arastirma ve Uygulama Hastanesi Merkez Laboratuvari, Address: Umuttepe 413 80 Kocaeli ,TURKEY | Initial Entry |

3. Collection Date:

| Date   | Location        | User                          | Value                             | Reason        |
|--|-----------------|-------------------------------|-----------------------------------|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Nov/20/2020 | Initial Entry |

4. Specimen Type:

| Date   | Location        | User                    | Value                       | Reason        |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>BLOOD | Initial Entry |

5.a

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Sponsor-Defined Identifier:<br>Test:: Hemoglobin_PX1<br>Result:: 14.94<br>Not Done:: | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | <b>Lab Normal Range:</b> <i>Low</i><br>12.5<br><br><i>High</i><br>16.3<br><br><i>Unit</i><br>g/dL |  |
|--|--|--|---|--|

5.a Sponsor ID:

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>1 | Initial Entry |

5.a Test:

| Date   | Location        | User                          | Value                                | Reason        |
|--|-----------------|-------------------------------|--------------------------------------|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <u>Data Entry:</u><br>Hemoglobin_PX1 | Initial Entry |

5.a Result:

| Date   | Location        | User                          | Value                       | Reason        |
|--|-----------------|-------------------------------|-----------------------------|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <u>Data Entry:</u><br>14.94 | Initial Entry |

5.a LNMT

| Date   | Location        | User                          | Value  | Reason        |
|--|-----------------|-------------------------------|--|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <u>Data Entry:</u><br><i>Low</i><br>12.5<br><br><i>High</i><br>16.3<br><br><i>Unit</i><br>g/dL | Initial Entry |

5.b

| Date   | Location        | User                    | Value              | Reason        |
|--|-----------------|-------------------------|--------------------|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u> | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Hematocrit_P X2<br><b>Result::</b> 42.58<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 36.7<br><br><i>High</i> 47.1<br><br><i>Unit</i> % |  |
|--|--|--|--|--|

5.b Sponsor ID:

| Date                                      | Location        | User                 | Value                   | Reason        |
|---|-----------------|----------------------|-------------------------|---------------|
| Nov-23-2020 16:41:28 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br>2 | Initial Entry |

5.b Test:

| Date                                      | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Nov-23-2020 16:41:28 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b><br>Hematocrit_PX2 | Initial Entry |

5.b Result:

| Date                                      | Location        | User                    | Value                       | Reason        |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Nov-23-2020 16:41:28 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b><br>42.58 | Initial Entry |

5.b LNMT

| Date                                      | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Nov-23-2020 16:41:28 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b><br><i>Low</i> 36.7<br><br><i>High</i> 47.1<br><br><i>Unit</i> % | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.c

| Date   | Location        | User                    | Value   | Reason              |
|--|-----------------|-------------------------|---|---------------------|
| Nov-23-2020 21:27:50<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Erythrocytes_PX3<br><b>Result::</b> 5.060<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 4.06<br><br><i>High</i> 5.63<br><br><i>Unit</i> 10 <sup>12</sup> /L | Transcription Error |
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Erythrocytes_PX3<br><b>Result::</b> 0.001<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 0<br><br><i>High</i> 0.5<br><br><i>Unit</i> 10 <sup>3</sup> /uL     | Initial Entry       |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.c Sponsor ID:

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>3 | Initial Entry |

5.c Test:

| Date   | Location        | User                       | Value                                  | Reason        |
|--|-----------------|----------------------------|--|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Erythrocytes_PX3 | Initial Entry |

5.c Result:

| Date   | Location        | User                       | Value                       | Reason              |
|--|-----------------|----------------------------|-----------------------------|---------------------|
| Nov-23-2020 21:27:50<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br>5.060 | Transcription Error |
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>0.001 | Initial Entry       |

5.c LNMT

| Date   | Location        | User                       | Value   | Reason              |
|--|-----------------|----------------------------|---|---------------------|
| Nov-23-2020 21:27:50<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br><i>Low</i><br>4.06<br><i>High</i><br>5.63<br><i>Unit</i><br>10 <sup>12</sup> /L | Transcription Error |
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br><i>Low</i><br>0<br><i>High</i><br>0.5<br><i>Unit</i><br>10 <sup>3</sup> /uL     | Initial Entry       |

5.d

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

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

**Site No:** 1217

**Subject No:** 12171044

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

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

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

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

|  |                 |                         |   |               |
|--|-----------------|-------------------------|---|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACVOPFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Platelets_P<br>X5<br><b>Result::</b> 208.8<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>152<br><br><i>High</i><br>348<br><br><i>Unit</i><br>10 <sup>3</sup> /uL | Initial Entry |
|--|-----------------|-------------------------|---|---------------|



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.d Sponsor ID:

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>5 | Initial Entry |

5.d Test:

| Date   | Location        | User                          | Value                               | Reason        |
|--|-----------------|-------------------------------|-------------------------------------|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Platelets_PX5 | Initial Entry |

5.d Result:

| Date   | Location        | User                          | Value                       | Reason        |
|--|-----------------|-------------------------------|-----------------------------|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>208.8 | Initial Entry |

5.d LNMT

| Date   | Location        | User                          | Value   | Reason        |
|--|-----------------|-------------------------------|---|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><br><i>Low</i><br>152<br><br><i>High</i><br>348<br><br><i>Unit</i><br>10^3/uL | Initial Entry |

5.e

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Leukocytes_P<br>X7<br><b>Result::</b> 10.915<br><b>Not Done::</b> | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | <b>Lab Normal Range:</b> <i>Low</i><br>3.6<br><br><i>High</i><br>10.2<br><br><i>Unit</i><br>10 <sup>3</sup> /uL |  |
|--|--|--|---|--|

5.e Sponsor ID:

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>7 | Initial Entry |

5.e Test:

| Date   | Location        | User                          | Value                                | Reason        |
|--|-----------------|-------------------------------|--------------------------------------|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Leukocytes_PX7 | Initial Entry |

5.e Result:

| Date   | Location        | User                          | Value                        | Reason        |
|--|-----------------|-------------------------------|------------------------------|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>10.915 | Initial Entry |

5.e LNMT

| Date   | Location        | User                          | Value  | Reason        |
|--|-----------------|-------------------------------|--|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><i>Low</i><br>3.6<br><br><i>High</i><br>10.2<br><br><i>Unit</i><br>10 <sup>3</sup> /uL | Initial Entry |

5.f

| Date   | Location        | User                    | Value              | Reason        |
|--|-----------------|-------------------------|--------------------|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b> | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Neutrophils_PX608<br><b>Result::</b> 8.717<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 1.7<br><i>High</i> 7.6<br><br><i>Unit</i> 10 <sup>3</sup> /uL |  |
|--|--|--|--|--|

5.f Sponsor ID:

| Date                                      | Location        | User                 | Value                  | Reason        |
|---|-----------------|----------------------|------------------------|---------------|
| Nov-23-2020 16:41:28 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b> 608 | Initial Entry |

5.f Test:

| Date                                      | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Nov-23-2020 16:41:28 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b> Neutrophils_PX608 | Initial Entry |

5.f Result:

| Date                                      | Location        | User                    | Value                    | Reason        |
|---|-----------------|-------------------------|--------------------------|---------------|
| Nov-23-2020 16:41:28 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b> 8.717 | Initial Entry |

5.f LNMT

| Date                                      | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Nov-23-2020 16:41:28 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b><br><i>Low</i> 1.7<br><br><i>High</i> 7.6<br><br><i>Unit</i> 10 <sup>3</sup> /uL | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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

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

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

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 13:11

5.g

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 609<br><b>Test::</b> Eosinophils_P<br>X609<br><b>Result::</b> 0.001<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>0<br><br><i>High</i><br>0.5<br><br><i>Unit</i><br>10^3/uL | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.g Sponsor ID:

| Date   | Location        | User                    | Value                     | Reason        |
|--|-----------------|-------------------------|---------------------------|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>609 | Initial Entry |

5.g Test:

| Date   | Location        | User                          | Value                                   | Reason        |
|--|-----------------|-------------------------------|---|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Eosinophils_PX609 | Initial Entry |

5.g Result:

| Date   | Location        | User                          | Value                       | Reason        |
|--|-----------------|-------------------------------|-----------------------------|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>0.001 | Initial Entry |

5.g LNMT

| Date   | Location        | User                          | Value   | Reason        |
|--|-----------------|-------------------------------|---|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><br><i>Low</i><br>0<br><br><i>High</i><br>0.5<br><br><i>Unit</i><br>10^3/uL | Initial Entry |

5.h

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 612<br><b>Test::</b> Monocytes_PX<br>612<br><b>Result::</b> 0.939<br><b>Not Done::</b> | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Lab Normal Range:</b> <i>Low</i><br>0.3<br><br><i>High</i><br>1.1<br><br><i>Unit</i><br>10 <sup>3</sup> /uL |  |
|--|--|--|--|--|

5.h Sponsor ID:

| Date   | Location        | User                    | Value                     | Reason        |
|--|-----------------|-------------------------|---------------------------|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>612 | Initial Entry |

5.h Test:

| Date   | Location        | User                          | Value                                 | Reason        |
|--|-----------------|-------------------------------|---------------------------------------|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Monocytes_PX612 | Initial Entry |

5.h Result:

| Date   | Location        | User                          | Value                       | Reason        |
|--|-----------------|-------------------------------|-----------------------------|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>0.939 | Initial Entry |

5.h LNMT

| Date   | Location        | User                          | Value   | Reason        |
|--|-----------------|-------------------------------|---|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><i>Low</i><br>0.3<br><br><i>High</i><br>1.1<br><br><i>Unit</i><br>10 <sup>3</sup> /uL | Initial Entry |

5.i

| Date   | Location        | User                    | Value              | Reason        |
|--|-----------------|-------------------------|--------------------|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b> | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | <b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Basophils_PX610<br><b>Result::</b> 0.031<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>0<br><br><i>High</i><br>0.1<br><br><i>Unit</i><br>10^3/uL |  |
|--|--|--|---|--|

5.i Sponsor ID:

| Date                                      | Location        | User                 | Value                     | Reason        |
|---|-----------------|----------------------|---------------------------|---------------|
| Nov-23-2020 16:41:28 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br>610 | Initial Entry |

5.i Test:

| Date                                      | Location        | User                    | Value                                 | Reason        |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Nov-23-2020 16:41:28 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b><br>Basophils_PX610 | Initial Entry |

5.i Result:

| Date                                      | Location        | User                    | Value                       | Reason        |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Nov-23-2020 16:41:28 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b><br>0.031 | Initial Entry |

5.i LNMT

| Date                                      | Location        | User                    | Value   | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Nov-23-2020 16:41:28 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b><br><i>Low</i><br>0<br><br><i>High</i><br>0.1<br><br><i>Unit</i><br>10^3/uL | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

5.j

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 611<br><b>Test::</b> Lymphocytes_P<br>X611<br><b>Result::</b> 1.226<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>1<br><br><i>High</i><br>3.2<br><br><i>Unit</i><br>10^3/uL | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**5.j Sponsor ID:**

| Date   | Location        | User                    | Value                     | Reason        |
|--|-----------------|-------------------------|---------------------------|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>611 | Initial Entry |

**5.j Test:**

| Date   | Location        | User                          | Value                                   | Reason        |
|--|-----------------|-------------------------------|---|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Lymphocytes_PX611 | Initial Entry |

**5.j Result:**

| Date   | Location        | User                          | Value                       | Reason        |
|--|-----------------|-------------------------------|-----------------------------|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>1.226 | Initial Entry |

**5.j LNMT**

| Date   | Location        | User                          | Value   | Reason        |
|--|-----------------|-------------------------------|---|---------------|
| Nov-23-2020 16:41:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><i>Low</i><br>1<br><i>High</i><br>3.2<br><i>Unit</i><br>10 <sup>3</sup> /uL | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form Version: 10-Oct-2020 16:02

Site No: 1217

Subject No: 12171044

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Lab Panel:**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>HEMATOLOGY | Initial Entry |

**2. Laboratory Name and Address**

| Date   | Location        | User                          | Value   | Reason        |
|--|-----------------|-------------------------------|---|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Lab Name:Kocaeli Universitesi Arastirma ve Uygulama Hastanesi Merkez Laboratuvari, Address: Umuttepe 413 80 Kocaeli ,TURKEY | Initial Entry |

**3. Collection Date:**

| Date   | Location        | User                          | Value                             | Reason        |
|--|-----------------|-------------------------------|-----------------------------------|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Nov/23/2020 | Initial Entry |

**4. Specimen Type:**

| Date   | Location        | User                    | Value                       | Reason        |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>BLOOD | Initial Entry |

**5.a**

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Hemoglobin_PX1<br><b>Result::</b> 14.81<br><b>Not Done::</b> | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | <b>Lab Normal Range:</b> <i>Low</i><br>12.5<br><br><i>High</i><br>16.3<br><br><i>Unit</i><br>g/dL |  |
|--|--|--|---|--|

5.a Sponsor ID:

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>1 | Initial Entry |

5.a Test:

| Date   | Location        | User                          | Value                                | Reason        |
|--|-----------------|-------------------------------|--------------------------------------|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <u>Data Entry:</u><br>Hemoglobin_PX1 | Initial Entry |

5.a Result:

| Date   | Location        | User                          | Value                       | Reason        |
|--|-----------------|-------------------------------|-----------------------------|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <u>Data Entry:</u><br>14.81 | Initial Entry |

5.a LNMT

| Date   | Location        | User                          | Value  | Reason        |
|--|-----------------|-------------------------------|--|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <u>Data Entry:</u><br><i>Low</i><br>12.5<br><br><i>High</i><br>16.3<br><br><i>Unit</i><br>g/dL | Initial Entry |

5.b

| Date   | Location        | User                    | Value              | Reason        |
|--|-----------------|-------------------------|--------------------|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u> | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Hematocrit_P X2<br><b>Result::</b> 42.79<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 36.7<br><br><i>High</i> 47.1<br><br><i>Unit</i> % |  |
|--|--|--|--|--|

5.b Sponsor ID:

| Date                                      | Location        | User                 | Value                   | Reason        |
|---|-----------------|----------------------|-------------------------|---------------|
| Nov-23-2020 16:47:21 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br>2 | Initial Entry |

5.b Test:

| Date                                      | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Nov-23-2020 16:47:21 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b><br>Hematocrit_PX2 | Initial Entry |

5.b Result:

| Date                                      | Location        | User                    | Value                       | Reason        |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Nov-23-2020 16:47:21 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b><br>42.79 | Initial Entry |

5.b LNMT

| Date                                      | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Nov-23-2020 16:47:21 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b><br><i>Low</i> 36.7<br><br><i>High</i> 47.1<br><br><i>Unit</i> % | Initial Entry |

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.c

| Date   | Location        | User                    | Value  | Reason              |
|--|-----------------|-------------------------|--|---------------------|
| Nov-23-2020 21:29:44<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Erythrocytes_<br>PX3<br><b>Result::</b> 5.152<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>4.06<br><br><i>High</i><br>5.63<br><br><i>Unit</i><br>10^12/L | Transcription Error |
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Erythrocytes_<br>PX3<br><b>Result::</b> 0.053<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>0<br><br><i>High</i><br>0.5<br><br><i>Unit</i><br>10^3/uL     | Initial Entry       |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.c Sponsor ID:

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>3 | Initial Entry |

5.c Test:

| Date   | Location        | User                          | Value                                  | Reason        |
|--|-----------------|-------------------------------|--|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Erythrocytes_PX3 | Initial Entry |

5.c Result:

| Date   | Location        | User                          | Value                       | Reason              |
|--|-----------------|-------------------------------|-----------------------------|---------------------|
| Nov-23-2020 21:29:44<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b><br>5.152 | Transcription Error |
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>0.053 | Initial Entry       |

5.c LNMT

| Date   | Location        | User                          | Value   | Reason              |
|--|-----------------|-------------------------------|---|---------------------|
| Nov-23-2020 21:29:44<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b><br><i>Low</i><br>4.06<br><i>High</i><br>5.63<br><i>Unit</i><br>10 <sup>12</sup> /L | Transcription Error |
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><i>Low</i><br>0<br><i>High</i><br>0.5<br><i>Unit</i><br>10 <sup>3</sup> /uL     | Initial Entry       |

5.d

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

**Form Version:** 10-Oct-2020 16:02

**Site No:** 1217

**Subject No:** 12171044

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

|  |                 |                         |   |               |
|--|-----------------|-------------------------|---|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACVOPFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Platelets_P<br>X5<br><b>Result::</b> 304.7<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>152<br><br><i>High</i><br>348<br><br><i>Unit</i><br>10 <sup>3</sup> /uL | Initial Entry |
|--|-----------------|-------------------------|---|---------------|

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.d Sponsor ID:

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>5 | Initial Entry |

5.d Test:

| Date   | Location        | User                          | Value                               | Reason        |
|--|-----------------|-------------------------------|-------------------------------------|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Platelets_PX5 | Initial Entry |

5.d Result:

| Date   | Location        | User                          | Value                       | Reason        |
|--|-----------------|-------------------------------|-----------------------------|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>304.7 | Initial Entry |

5.d LNMT

| Date   | Location        | User                          | Value   | Reason        |
|--|-----------------|-------------------------------|---|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><br><i>Low</i><br>152<br><br><i>High</i><br>348<br><br><i>Unit</i><br>10 <sup>3</sup> /uL | Initial Entry |

5.e

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Leukocytes_P<br>X7<br><b>Result::</b> 7.710<br><b>Not Done::</b> | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | <b>Lab Normal Range:</b> <i>Low</i><br>3.6<br><br><i>High</i><br>10.2<br><br><i>Unit</i><br>10 <sup>3</sup> /uL |  |
|--|--|--|---|--|

5.e Sponsor ID:

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>7 | Initial Entry |

5.e Test:

| Date   | Location        | User                          | Value                                | Reason        |
|--|-----------------|-------------------------------|--------------------------------------|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Leukocytes_PX7 | Initial Entry |

5.e Result:

| Date   | Location        | User                          | Value                       | Reason        |
|--|-----------------|-------------------------------|-----------------------------|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>7.710 | Initial Entry |

5.e LNMT

| Date   | Location        | User                          | Value  | Reason        |
|--|-----------------|-------------------------------|--|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><i>Low</i><br>3.6<br><br><i>High</i><br>10.2<br><br><i>Unit</i><br>10 <sup>3</sup> /uL | Initial Entry |

5.f

| Date   | Location        | User                    | Value              | Reason        |
|--|-----------------|-------------------------|--------------------|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b> | Initial Entry |

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Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Neutrophils_PX608<br><b>Result::</b> 5.273<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 1.7<br><i>High</i> 7.6<br><i>Unit</i> 10 <sup>3</sup> /uL |  |
|--|--|--|--|--|

5.f Sponsor ID:

| Date                                      | Location        | User                 | Value                  | Reason        |
|---|-----------------|----------------------|------------------------|---------------|
| Nov-23-2020 16:47:21 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b> 608 | Initial Entry |

5.f Test:

| Date                                      | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Nov-23-2020 16:47:21 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b> Neutrophils_PX608 | Initial Entry |

5.f Result:

| Date                                      | Location        | User                    | Value                    | Reason        |
|---|-----------------|-------------------------|--------------------------|---------------|
| Nov-23-2020 16:47:21 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b> 5.273 | Initial Entry |

5.f LNMT

| Date                                      | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Nov-23-2020 16:47:21 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b><br><i>Low</i> 1.7<br><i>High</i> 7.6<br><i>Unit</i> 10 <sup>3</sup> /uL | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

5.g

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 609<br><b>Test::</b> Eosinophils_P<br>X609<br><b>Result::</b> 0.053<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>0<br><br><i>High</i><br>0.5<br><br><i>Unit</i><br>10^3/uL | Initial Entry |

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.g Sponsor ID:

| Date   | Location        | User                    | Value                     | Reason        |
|--|-----------------|-------------------------|---------------------------|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>609 | Initial Entry |

5.g Test:

| Date   | Location        | User                          | Value                                   | Reason        |
|--|-----------------|-------------------------------|---|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Eosinophils_PX609 | Initial Entry |

5.g Result:

| Date   | Location        | User                          | Value                       | Reason        |
|--|-----------------|-------------------------------|-----------------------------|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>0.053 | Initial Entry |

5.g LNMT

| Date   | Location        | User                          | Value   | Reason        |
|--|-----------------|-------------------------------|---|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><br><i>Low</i><br>0<br><br><i>High</i><br>0.5<br><br><i>Unit</i><br>10^3/uL | Initial Entry |

5.h

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 612<br><b>Test::</b> Monocytes_PX<br>612<br><b>Result::</b> 0.478<br><b>Not Done::</b> | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Lab Normal Range:</b> <i>Low</i><br>0.3<br><br><i>High</i><br>1.1<br><br><i>Unit</i><br>10 <sup>3</sup> /uL |  |
|--|--|--|--|--|

5.h Sponsor ID:

| Date   | Location        | User                    | Value                     | Reason        |
|--|-----------------|-------------------------|---------------------------|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>612 | Initial Entry |

5.h Test:

| Date   | Location        | User                          | Value                                 | Reason        |
|--|-----------------|-------------------------------|---------------------------------------|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <u>Data Entry:</u><br>Monocytes_PX612 | Initial Entry |

5.h Result:

| Date   | Location        | User                          | Value                       | Reason        |
|--|-----------------|-------------------------------|-----------------------------|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <u>Data Entry:</u><br>0.478 | Initial Entry |

5.h LNMT

| Date   | Location        | User                          | Value   | Reason        |
|--|-----------------|-------------------------------|---|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <u>Data Entry:</u><br><i>Low</i><br>0.3<br><br><i>High</i><br>1.1<br><br><i>Unit</i><br>10 <sup>3</sup> /uL | Initial Entry |

5.i

| Date   | Location        | User                | Value              | Reason              |
|--|-----------------|---------------------|--------------------|---------------------|
| Nov-23-2020 21:30:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u> | Transcription Error |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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Subject No: 12171044

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

|   |                 |                      |   |               |
|---|-----------------|----------------------|---|---------------|
|   |                 | (b) (4), (b) (6)     | <b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Basophils_PX 610<br><b>Result::</b> 0.048<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 0<br><i>High</i> 0.1<br><br><i>Unit</i><br>10^3/uL                        |               |
| Nov-23-2020 16:47:21 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Basophils_PX 610<br><b>Result::</b> 0.048<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 0<br><i>High</i> 0.01<br><br><i>Unit</i><br>10^3/uL | Initial Entry |

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Header Text: C4591001

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Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.i Sponsor ID:

| Date   | Location        | User                    | Value                     | Reason        |
|--|-----------------|-------------------------|---------------------------|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>610 | Initial Entry |

5.i Test:

| Date   | Location        | User                       | Value                                 | Reason        |
|--|-----------------|----------------------------|---------------------------------------|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Basophils_PX610 | Initial Entry |

5.i Result:

| Date   | Location        | User                       | Value                       | Reason        |
|--|-----------------|----------------------------|-----------------------------|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>0.048 | Initial Entry |

5.i LNMT

| Date   | Location        | User                       | Value  | Reason              |
|--|-----------------|----------------------------|--|---------------------|
| Nov-23-2020 21:30:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br><i>Low</i><br>0<br><br><i>High</i><br>0.1<br><br><i>Unit</i><br>10 <sup>3</sup> /uL  | Transcription Error |
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br><i>Low</i><br>0<br><br><i>High</i><br>0.01<br><br><i>Unit</i><br>10 <sup>3</sup> /uL | Initial Entry       |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

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| 5.j  |                 |                         |   |               |
|--|-----------------|-------------------------|---|---------------|
| Date   | Location        | User                    | Value   | Reason        |
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Lymphocytes_P<br>X611<br><b>Result::</b> 1.858<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>1<br><br><i>High</i><br>3.2<br><br><i>Unit</i><br>10^3/uL | Initial Entry |

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Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.j Sponsor ID:

| Date   | Location        | User                    | Value                     | Reason        |
|--|-----------------|-------------------------|---------------------------|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>611 | Initial Entry |

5.j Test:

| Date   | Location        | User                          | Value                                   | Reason        |
|--|-----------------|-------------------------------|---|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Lymphocytes_PX611 | Initial Entry |

5.j Result:

| Date   | Location        | User                          | Value                       | Reason        |
|--|-----------------|-------------------------------|-----------------------------|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>1.858 | Initial Entry |

5.j LNMT

| Date   | Location        | User                          | Value   | Reason        |
|--|-----------------|-------------------------------|---|---------------|
| Nov-23-2020 16:47:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><i>Low</i><br>1<br><br><i>High</i><br>3.2<br><br><i>Unit</i><br>10^3/uL | Initial Entry |

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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Subject No: 12171044

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Lab Panel:**

| Date   | Location        | User                    | Value                            | Reason        |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>HEMATOLOGY | Initial Entry |

**2. Laboratory Name and Address**

| Date   | Location        | User                          | Value  | Reason        |
|--|-----------------|-------------------------------|--|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Kocaeli Universitesi Arastirma ve Uygulama Hastanesi Merkez Laboratuvarı, Umuttepe 41380 Kocaeli ,TURKEY | Initial Entry |

**3. Collection Date:**

| Date   | Location        | User                          | Value                             | Reason        |
|--|-----------------|-------------------------------|-----------------------------------|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Nov/29/2020 | Initial Entry |

**4. Specimen Type:**

| Date   | Location        | User                    | Value                       | Reason        |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>BLOOD | Initial Entry |

**5.a**

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Sponsor-Defined Identifier:<br>Test:: Hemoglobin_PX1<br>Result:: 14.53<br>Not Done:: | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | <b>Lab Normal Range:</b> <i>Low</i><br>12.5<br><br><i>High</i><br>16.3<br><br><i>Unit</i><br>g/dL |  |
|--|--|--|---|--|

5.a Sponsor ID:

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>1 | Initial Entry |

5.a Test:

| Date   | Location        | User                          | Value                                | Reason        |
|--|-----------------|-------------------------------|--------------------------------------|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <u>Data Entry:</u><br>Hemoglobin_PX1 | Initial Entry |

5.a Result:

| Date   | Location        | User                          | Value                       | Reason        |
|--|-----------------|-------------------------------|-----------------------------|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <u>Data Entry:</u><br>14.53 | Initial Entry |

5.a LNMT

| Date   | Location        | User                          | Value  | Reason        |
|--|-----------------|-------------------------------|--|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <u>Data Entry:</u><br><i>Low</i><br>12.5<br><br><i>High</i><br>16.3<br><br><i>Unit</i><br>g/dL | Initial Entry |

5.b

| Date   | Location        | User                    | Value              | Reason        |
|--|-----------------|-------------------------|--------------------|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u> | Initial Entry |

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Hematocrit_P X2<br><b>Result::</b> 43.33<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 36.7<br><br><i>High</i> 47.1<br><br><i>Unit</i> % |  |
|--|--|--|--|--|

5.b Sponsor ID:

| Date                                      | Location        | User                 | Value                   | Reason        |
|---|-----------------|----------------------|-------------------------|---------------|
| Dec-03-2020 10:35:23 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b><br>2 | Initial Entry |

5.b Test:

| Date                                      | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Dec-03-2020 10:35:23 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b><br>Hematocrit_PX2 | Initial Entry |

5.b Result:

| Date                                      | Location        | User                    | Value                       | Reason        |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Dec-03-2020 10:35:23 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b><br>43.33 | Initial Entry |

5.b LNMT

| Date                                      | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Dec-03-2020 10:35:23 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b><br><i>Low</i> 36.7<br><br><i>High</i> 47.1<br><br><i>Unit</i> % | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

5.c

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Erythrocytes_<br>PX3<br><b>Result::</b> 5.111<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>4.06<br><br><i>High</i><br>5.63<br><br><i>Unit</i><br>10 <sup>12</sup> /L | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.c Sponsor ID:

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>3 | Initial Entry |

5.c Test:

| Date   | Location        | User                          | Value                                  | Reason        |
|--|-----------------|-------------------------------|--|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Erythrocytes_PX3 | Initial Entry |

5.c Result:

| Date   | Location        | User                          | Value                       | Reason        |
|--|-----------------|-------------------------------|-----------------------------|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>5.111 | Initial Entry |

5.c LNMT

| Date   | Location        | User                          | Value   | Reason        |
|--|-----------------|-------------------------------|---|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><br><i>Low</i><br>4.06<br><br><i>High</i><br>5.63<br><br><i>Unit</i><br>10 <sup>12</sup> /L | Initial Entry |

5.d

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Platelets_P<br>X5<br><b>Result::</b> 397.6<br><b>Not Done::</b> | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form Version: 10-Oct-2020 16:02

Site No: 1217

Subject No: 12171044

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |                          |                                    |  |
|--|--|--|--------------------------|------------------------------------|--|
|  |  |  | <b>Lab Normal Range:</b> | <i>Low</i><br>152                  |  |
|  |  |  |                          | <i>High</i><br>348                 |  |
|  |  |  |                          | <i>Unit</i><br>10 <sup>3</sup> /uL |  |

5.d Sponsor ID:

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>5 | Initial Entry |

5.d Test:

| Date   | Location        | User                          | Value                               | Reason        |
|--|-----------------|-------------------------------|-------------------------------------|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <u>Data Entry:</u><br>Platelets_PX5 | Initial Entry |

5.d Result:

| Date   | Location        | User                          | Value                       | Reason        |
|--|-----------------|-------------------------------|-----------------------------|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <u>Data Entry:</u><br>397.6 | Initial Entry |

5.d LNMT

| Date   | Location        | User                          | Value   | Reason        |
|--|-----------------|-------------------------------|---|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <u>Data Entry:</u><br><i>Low</i><br>152<br><i>High</i><br>348<br><i>Unit</i><br>10 <sup>3</sup> /uL | Initial Entry |

5.e

| Date   | Location        | User                    | Value              | Reason        |
|--|-----------------|-------------------------|--------------------|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u> | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | <b>Sponsor-Defined Identifier:</b><br><b>Test::</b> Leukocytes_PX7<br><b>Result::</b> 18.281<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 3.6<br><br><i>High</i> 10.2<br><br><i>Unit</i> 10^3/uL |  |
|--|--|--|---|--|

5.e Sponsor ID:

| Date                                      | Location        | User                 | Value                | Reason        |
|---|-----------------|----------------------|----------------------|---------------|
| Dec-03-2020 10:35:23 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b> 7 | Initial Entry |

5.e Test:

| Date                                      | Location        | User                    | Value                             | Reason        |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Dec-03-2020 10:35:23 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b> Leukocytes_PX7 | Initial Entry |

5.e Result:

| Date                                      | Location        | User                    | Value                     | Reason        |
|---|-----------------|-------------------------|---------------------------|---------------|
| Dec-03-2020 10:35:23 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b> 18.281 | Initial Entry |

5.e LNMT

| Date                                      | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Dec-03-2020 10:35:23 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b> <i>Low</i> 3.6<br><br><i>High</i> 10.2<br><br><i>Unit</i> 10^3/uL | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

5.f

| Date   | Location        | User                    | Value  | Reason        |
|--|-----------------|-------------------------|--|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 608<br><b>Test::</b> Neutrophils_P<br>X608<br><b>Result::</b> 13.698<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>1.7<br><i>High</i><br>7.6<br><i>Unit</i><br>10^3/uL | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.f Sponsor ID:

| Date   | Location        | User                    | Value                     | Reason        |
|--|-----------------|-------------------------|---------------------------|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>608 | Initial Entry |

5.f Test:

| Date   | Location        | User                          | Value                                   | Reason        |
|--|-----------------|-------------------------------|---|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Neutrophils_PX608 | Initial Entry |

5.f Result:

| Date   | Location        | User                          | Value                        | Reason        |
|--|-----------------|-------------------------------|------------------------------|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>13.698 | Initial Entry |

5.f LNMT

| Date   | Location        | User                          | Value   | Reason        |
|--|-----------------|-------------------------------|---|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><br><i>Low</i><br>1.7<br><br><i>High</i><br>7.6<br><br><i>Unit</i><br>10 <sup>3</sup> /uL | Initial Entry |

5.g

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 609<br><b>Test::</b> Eosinophils_P<br>X609<br><b>Result::</b> 0.086<br><b>Not Done::</b> | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Lab Normal Range:</b> <i>Low</i><br>0<br><br><i>High</i><br>0.5<br><br><i>Unit</i><br>10 <sup>3</sup> /uL |  |
|--|--|--|--|--|

5.g Sponsor ID:

| Date   | Location        | User                    | Value                     | Reason        |
|--|-----------------|-------------------------|---------------------------|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>609 | Initial Entry |

5.g Test:

| Date   | Location        | User                          | Value                                   | Reason        |
|--|-----------------|-------------------------------|---|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Eosinophils_PX609 | Initial Entry |

5.g Result:

| Date   | Location        | User                          | Value                       | Reason        |
|--|-----------------|-------------------------------|-----------------------------|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>0.086 | Initial Entry |

5.g LNMT

| Date   | Location        | User                          | Value   | Reason        |
|--|-----------------|-------------------------------|---|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><i>Low</i><br>0<br><br><i>High</i><br>0.5<br><br><i>Unit</i><br>10 <sup>3</sup> /uL | Initial Entry |

5.h

| Date   | Location        | User                    | Value              | Reason        |
|--|-----------------|-------------------------|--------------------|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b> | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | <b>Sponsor-Defined Identifier:</b> 612<br><b>Test::</b> Monocytes_PX 612<br><b>Result::</b> 1.327<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i> 0.3<br><br><i>High</i> 1.1<br><br><i>Unit</i> 10 <sup>3</sup> /uL |  |
|--|--|--|---|--|

5.h Sponsor ID:

| Date                                      | Location        | User                 | Value                  | Reason        |
|---|-----------------|----------------------|------------------------|---------------|
| Dec-03-2020 10:35:23 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc (autocalc) | <b>Data Entry:</b> 612 | Initial Entry |

5.h Test:

| Date                                      | Location        | User                    | Value                              | Reason        |
|---|-----------------|-------------------------|------------------------------------|---------------|
| Dec-03-2020 10:35:23 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b> Monocytes_PX612 | Initial Entry |

5.h Result:

| Date                                      | Location        | User                    | Value                    | Reason        |
|---|-----------------|-------------------------|--------------------------|---------------|
| Dec-03-2020 10:35:23 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b> 1.327 | Initial Entry |

5.h LNMT

| Date                                      | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Dec-03-2020 10:35:23 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b><br><i>Low</i> 0.3<br><br><i>High</i> 1.1<br><br><i>Unit</i> 10 <sup>3</sup> /uL | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

5.i

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 610<br><b>Test::</b> Basophils_PX<br>610<br><b>Result::</b> 0.060<br><b>Not Done::</b><br><b>Lab Normal Range:</b> <i>Low</i><br>0<br><br><i>High</i><br>0.1<br><br><i>Unit</i><br>10^3/uL | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

5.i Sponsor ID:

| Date   | Location        | User                    | Value                     | Reason        |
|--|-----------------|-------------------------|---------------------------|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>610 | Initial Entry |

5.i Test:

| Date   | Location        | User                          | Value                                 | Reason        |
|--|-----------------|-------------------------------|---------------------------------------|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Basophils_PX610 | Initial Entry |

5.i Result:

| Date   | Location        | User                          | Value                       | Reason        |
|--|-----------------|-------------------------------|-----------------------------|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>0.060 | Initial Entry |

5.i LNMT

| Date   | Location        | User                          | Value   | Reason        |
|--|-----------------|-------------------------------|---|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><br><i>Low</i><br>0<br><br><i>High</i><br>0.1<br><br><i>Unit</i><br>10 <sup>3</sup> /uL | Initial Entry |

5.j

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier:</b> 611<br><b>Test::</b> Lymphocytes_P<br>X611<br><b>Result::</b> 3.110<br><b>Not Done::</b> | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  | <b>Lab Normal Range:</b> <i>Low</i><br>1<br><br><i>High</i><br>3.2<br><br><i>Unit</i><br>10 <sup>3</sup> /uL |  |
|--|--|--|--|--|

5.j Sponsor ID:

| Date   | Location        | User                    | Value                     | Reason        |
|--|-----------------|-------------------------|---------------------------|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>611 | Initial Entry |

5.j Test:

| Date   | Location        | User                          | Value                                   | Reason        |
|--|-----------------|-------------------------------|---|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Lymphocytes_PX611 | Initial Entry |

5.j Result:

| Date   | Location        | User                          | Value                       | Reason        |
|--|-----------------|-------------------------------|-----------------------------|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>3.110 | Initial Entry |

5.j LNMT

| Date   | Location        | User                          | Value   | Reason        |
|--|-----------------|-------------------------------|---|---------------|
| Dec-03-2020 10:35:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br><i>Low</i><br>1<br><br><i>High</i><br>3.2<br><br><i>Unit</i><br>10 <sup>3</sup> /uL | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** VITAL SIGNS - COVID - Audit Trail

**Form Version:** 10-Oct-2020 15:59

**Form Status:**

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Date   | Location        | User                | Value        | Reason |
|--|-----------------|---------------------|--------------|--------|
| Nov-13-2020 14:54:32<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Form Created |        |



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** VITAL SIGNS - COVID - Audit Trail

**Form Version:** 10-Oct-2020 15:59

**Form Status:**

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Date   | Location        | User                | Value        | Reason |
|--|-----------------|---------------------|--------------|--------|
| Nov-24-2020 15:39:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Form Created |        |

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 Form: VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**I. Date:**

| Date   | Location        | User                      | Value                             | Reason  |
|--|-----------------|---------------------------|-----------------------------------|---|
| Nov-17-2020 08:58:32<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Closed                   | Response satisfies query  |
| Nov-16-2020 16:00:27<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Answered                 | Initial Entry   |
| Nov-16-2020 16:00:27<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>Nov/12/2020 | Initial Entry   |
| Nov-14-2020 09:11:42<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Opened                   | DM: The response for "Date" is missing. Kindly review and update. |

**2.a**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-13-2020 14:54:32<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Record Identifier::</b> 1<br><b>Systolic::</b> 13<br>0<br><b>Diastolic::</b> 80<br><b>Respiratory Rate in respirations/ minute:</b> 20<br><b>Heart Rate in beats/minute:</b> 95 | Initial Entry |

**2.a Record Identifier:**

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Nov-13-2020 14:54:32<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>1 | Initial Entry |

**2.a Systolic:**

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Nov-13-2020 14:54:32<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>130 | Initial Entry |

**2.a Diastolic:**

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:59

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-13-2020 14:54:32<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>80 | Initial Entry |

**2.a Respiratory Rate in respirations/minute:**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-13-2020 14:54:32<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>20 | Initial Entry |

**2.a Heart Rate in beats/minute:**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-13-2020 14:54:32<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>95 | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 Form: VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Date:**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Nov-24-2020 15:39:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/20/2020 | Initial Entry |

**2.a**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-24-2020 15:39:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Record Identifier::</b> 1<br><b>Systolic::</b> 11<br>0<br><b>Diastolic::</b> 70<br><b>Respiratory Rate in respirations/<br/>minute:</b> 22<br><b>Heart Rate in beats/minute:</b> 80 | Initial Entry |

**2.a Record Identifier:**

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Nov-24-2020 15:39:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>1 | Initial Entry |

**2.a Systolic:**

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Nov-24-2020 15:39:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>110 | Initial Entry |

**2.a Diastolic:**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-24-2020 15:39:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>70 | Initial Entry |

**2.a Respiratory Rate in respirations/minute:**

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:59

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

|  |                 |                     |                          |               |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-24-2020 15:39:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>22 | Initial Entry |
|--|-----------------|---------------------|--------------------------|---------------|

**2.a Heart Rate in beats/minute:**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Nov-24-2020 15:39:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>80 | Initial Entry |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail

**Form Version:** 10-Oct-2020 16:04

**Form Status:**

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Date   | Location        | User                | Value        | Reason |
|--|-----------------|---------------------|--------------|--------|
| Nov-16-2020 16:39:56<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Form Created |        |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail

**Form Version:** 10-Oct-2020 16:04

**Form Status:**

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Date   | Location        | User                | Value        | Reason |
|--|-----------------|---------------------|--------------|--------|
| Nov-24-2020 15:37:55<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Form Created |        |

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**I. Date:**

| Date   | Location        | User                | Value                             | Reason              |
|--|-----------------|---------------------|-----------------------------------|---------------------|
| Nov-16-2020 16:40:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/11/2020 | Transcription Error |
| Nov-16-2020 16:39:56<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/12/2020 | Initial Entry       |

**2.a**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-16-2020 16:39:56<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Record Identifier::</b> 1<br><b>Oxygen Saturation:</b> 97.0 | Initial Entry |

**2.a Record Identifier:**

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Nov-16-2020 16:39:56<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>1 | Initial Entry |

**2.a SPO2 Pulse Oximetry %**

| Date   | Location        | User                | Value                      | Reason        |
|--|-----------------|---------------------|----------------------------|---------------|
| Nov-16-2020 16:39:56<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>97.0 | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Date:**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Nov-24-2020 15:37:55<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/20/2020 | Initial Entry |

**2.a**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-24-2020 15:37:55<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Record Identifier::</b> 1<br><b>Oxygen Saturation:</b> 94.0 | Initial Entry |

**2.a Record Identifier:**

| Date   | Location        | User                | Value                   | Reason        |
|--|-----------------|---------------------|-------------------------|---------------|
| Nov-24-2020 15:37:55<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>1 | Initial Entry |

**2.a SPO2 Pulse Oximetry %**

| Date   | Location        | User                | Value                      | Reason        |
|--|-----------------|---------------------|----------------------------|---------------|
| Nov-24-2020 15:37:55<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>94.0 | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** OXYGENATION PARAMETERS - Audit Trail

**Form Version:** 06-Jul-2020 21:52

**Form Status:**

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Date   | Location        | User                          | Value        | Reason |
|--|-----------------|-------------------------------|--------------|--------|
| Nov-23-2020 16:15:26<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Created |        |

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: OXYGENATION PARAMETERS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Date Time of Assessment:**

| Date   | Location        | User                       | Value                                   | Reason        |
|--|-----------------|----------------------------|---|---------------|
| Nov-23-2020 16:15:26<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Nov/20/2020 18:00 | Initial Entry |
| Nov-23-2020 16:06:48<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b>                      | Initial Entry |
| Nov-17-2020 18:19:58<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br>Not Done          | Initial Entry |

**2. Arterial Blood Gases PaO2 (mmHg):**

| Date   | Location        | User                       | Value                          | Reason        |
|--|-----------------|----------------------------|--------------------------------|---------------|
| Nov-23-2020 16:15:26<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>65       | Initial Entry |
| Nov-23-2020 16:06:48<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b>             | Initial Entry |
| Nov-17-2020 18:19:58<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br>Not Done | Initial Entry |

**3. FiO2 (Fraction of Inhaled Oxygen):**

| Date   | Location        | User                      | Value                      | Reason   |
|--|-----------------|---------------------------|----------------------------|--|
| Nov-24-2020 21:42:13<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Closed            | Response satisfies query   |
| Nov-24-2020 11:26:54<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Answered          | Initial Entry  |
| Nov-24-2020 11:26:54<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>0.69 | Initial Entry  |
| Nov-24-2020 09:36:33<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Opened            | DM: The response for "FiO2 (Fraction of Inhaled Oxygen)" is missing. Kindly review and update. |
| Nov-23-2020 16:06:48<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim           | <b>Data Entry:</b>         | Initial Entry  |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

|  |                 |                     |                                |               |
|--|-----------------|---------------------|--------------------------------|---------------|
|  |                 | (b) (4)             |                                |               |
| Nov-17-2020 18:19:58<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Audit Trail

**Form Version:** 06-Jul-2020 21:55

**Form Status:**

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**Subject No:** 12171044

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| Date   | Location        | User                          | Value        | Reason                          |
|--|-----------------|-------------------------------|--------------|---------------------------------|
| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Deleted | data was entered<br>by mistake. |
| Nov-16-2020 17:43:46<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | Form Created |                                 |

**Header Text:** C4591001

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**Form Version:** 06-Jul-2020 21:55

**Form Status:**

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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**Generated Time (GMT):** 29-Mar-2021 13:11

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| Date   | Location        | User                          | Value        | Reason                          |
|--|-----------------|-------------------------------|--------------|---------------------------------|
| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Deleted | data was entered<br>by mistake. |
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**Header Text:** C4591001

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**Form Version:** 06-Jul-2020 21:55

**Form Status:**

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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**Generated Time (GMT):** 29-Mar-2021 13:11

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| Date   | Location        | User                          | Value        | Reason                          |
|--|-----------------|-------------------------------|--------------|---------------------------------|
| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Deleted | data was entered<br>by mistake. |
| Nov-16-2020 17:48:03<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | Form Created |                                 |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Audit Trail

**Form Version:** 06-Jul-2020 21:55

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**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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**Generated Time (GMT):** 29-Mar-2021 13:11

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| Date   | Location        | User                          | Value        | Reason                          |
|--|-----------------|-------------------------------|--------------|---------------------------------|
| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Deleted | data was entered<br>by mistake. |
| Nov-18-2020 16:06:52<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | Form Created |                                 |



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Audit Trail

**Form Version:** 06-Jul-2020 21:55

**Form Status:**

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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**Generated Time (GMT):** 29-Mar-2021 13:11

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| Date   | Location        | User                          | Value        | Reason                          |
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| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Deleted | data was entered<br>by mistake. |
| Nov-18-2020 16:16:22<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | Form Created |                                 |

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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Audit Trail

**Form Version:** 06-Jul-2020 21:55

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**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

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| Date   | Location        | User                          | Value        | Reason                          |
|--|-----------------|-------------------------------|--------------|---------------------------------|
| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Deleted | data was entered<br>by mistake. |
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Audit Trail

**Form Version:** 06-Jul-2020 21:55

**Form Status:**

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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**Generated Time (GMT):** 29-Mar-2021 13:11

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| Date   | Location        | User                | Value        | Reason                 |
|--|-----------------|---------------------|--------------|------------------------|
| Nov-24-2020 14:06:21<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Form Deleted | Transcription<br>Error |
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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Audit Trail

**Form Version:** 06-Jul-2020 21:55

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**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

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| Date   | Location        | User                          | Value        | Reason                          |
|--|-----------------|-------------------------------|--------------|---------------------------------|
| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Deleted | data was entered<br>by mistake. |
| Nov-18-2020 16:27:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | Form Created |                                 |

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| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Deleted | data was entered<br>by mistake. |
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| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Deleted | data was entered<br>by mistake. |
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| Date   | Location        | User                          | Value        | Reason                          |
|--|-----------------|-------------------------------|--------------|---------------------------------|
| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Deleted | data was entered<br>by mistake. |
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**Form Version:** 06-Jul-2020 21:55

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**Site Name:** (1217) Kocaeli University Faculty of Medicine

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|--|-----------------|-------------------------------|--------------|---------------------------------|
| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Deleted | data was entered<br>by mistake. |
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**Header Text:** C4591001

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| Date   | Location        | User                          | Value        | Reason                          |
|--|-----------------|-------------------------------|--------------|---------------------------------|
| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Deleted | data was entered<br>by mistake. |
| Nov-23-2020 16:59:48<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Created |                                 |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Audit Trail

**Form Version:** 06-Jul-2020 21:55

**Form Status:**

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Date   | Location        | User                          | Value        | Reason                          |
|--|-----------------|-------------------------------|--------------|---------------------------------|
| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Deleted | data was entered<br>by mistake. |
| Nov-24-2020 11:57:06<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | Form Created |                                 |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Audit Trail

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**Generated Time (GMT):** 29-Mar-2021 13:11

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| Date   | Location        | User                          | Value        | Reason                          |
|--|-----------------|-------------------------------|--------------|---------------------------------|
| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Deleted | data was entered<br>by mistake. |
| Nov-24-2020 13:49:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | Form Created |                                 |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

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| Date   | Location        | User                          | Value        | Reason                          |
|--|-----------------|-------------------------------|--------------|---------------------------------|
| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Deleted | data was entered<br>by mistake. |
| Nov-24-2020 13:53:06<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | Form Created |                                 |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Audit Trail

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**Form Status:**

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**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

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**Generated Time (GMT):** 29-Mar-2021 13:11

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| Date   | Location        | User                          | Value        | Reason                          |
|--|-----------------|-------------------------------|--------------|---------------------------------|
| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Deleted | data was entered<br>by mistake. |
| Nov-24-2020 14:39:26<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | Form Created |                                 |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Audit Trail

**Form Version:** 06-Jul-2020 21:55

**Form Status:**

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

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| Date   | Location        | User                          | Value        | Reason                          |
|--|-----------------|-------------------------------|--------------|---------------------------------|
| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Deleted | data was entered<br>by mistake. |
| Nov-26-2020 11:53:16<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | Form Created |                                 |

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Audit Trail

**Form Version:** 06-Jul-2020 21:55

**Form Status:**

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

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| Date   | Location        | User                          | Value        | Reason                          |
|--|-----------------|-------------------------------|--------------|---------------------------------|
| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Deleted | data was entered<br>by mistake. |
| Dec-03-2020 14:01:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Created |                                 |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Audit Trail

**Form Version:** 06-Jul-2020 21:55

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**Site No:** 1217

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| Date   | Location        | User                          | Value        | Reason                          |
|--|-----------------|-------------------------------|--------------|---------------------------------|
| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Deleted | data was entered<br>by mistake. |
| Dec-03-2020 14:03:37<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Created |                                 |



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Deleted, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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1. What is the medication identifier?

| Date   | Location        | User                    | Value                          | Reason        |
|--|-----------------|-------------------------|--------------------------------|---------------|
| Nov-16-2020 17:43:46<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>1        | Initial Entry |
| Nov-16-2020 17:34:37<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | <u>Data Entry:</u>             | Initial Entry |
| Nov-13-2020 11:47:54<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | <u>Data Entry:</u><br>Not Done | Initial Entry |

2. Category:

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-16-2020 17:43:46<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>GENERAL CONCOMITANT MEDICATIONS | Initial Entry |
| Nov-16-2020 17:34:37<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | <u>Data Entry:</u>                                    | Initial Entry |
| Nov-13-2020 11:47:54<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | <u>Data Entry:</u><br>Not Done                        | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date   | Location        | User                    | Value                          | Reason        |
|--|-----------------|-------------------------|--------------------------------|---------------|
| Nov-16-2020 17:43:46<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>NO       | Initial Entry |
| Nov-16-2020 17:34:37<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | <u>Data Entry:</u>             | Initial Entry |
| Nov-13-2020 11:47:54<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)     | <u>Data Entry:</u><br>Not Done | Initial Entry |

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Deleted, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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| Date   | Location                                  | User                         | Value   | Reason   |
|--|---|------------------------------|---|--|
| Dec-08-2020<br>22:04:51<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)          | Query 2: Closed   | Response satisfies query   |
| Dec-07-2020<br>10:51:29<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | auto query<br>(autoquery)    | Query 2: Answered   | data was entered by mistake.   |
| Dec-04-2020<br>22:58:47<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | (b) (4), (b) (6)             | Query 2: Opened   | Clin: Only vasopressors are to be recorded on this CRF page. Please review and update CRF or else clarify. |
| Dec-04-2020<br>22:19:21<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | Salim Bouguermouh<br>(b) (4) | Query 2: Candidate  | Clin: Only vasopressors are to be recorded on this CRF page. Please review and update CRF or else clarify. |
| Nov-24-2020<br>13:48:31<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)          | <b>Data Entry:</b><br>Favipiravir (loading dose: 2x1600 mg, oral)           | Transcription Error  |
| Nov-16-2020<br>22:04:56<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle<br>(b) (4)     | Query 1: Closed   | Discrepancy has been closed.   |
| Nov-16-2020<br>19:55:08<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | auto query<br>(autoquery)    | Query 1: Answered   | Transcription Error  |
| Nov-16-2020<br>19:55:08<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)          | <b>Data Entry:</b><br>Favipiravir (loading dose: 2x1600 mg, 2x600 mg, oral) | Transcription Error  |
| Nov-16-2020<br>19:08:14<br>(UTC+03:00)             | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle<br>(b) (4)     | Query 1: Opened   | Spacing: Verbatim Term contains leading.   |

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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Form Status: Data Complete, Deleted, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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|  |                 |                     |   |  |
|--|-----------------|---------------------|---|--|
| Istanbul   |                 |                     |   | trailing or more than one consecutive space. |
| Nov-16-2020<br>17:43:46<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>favipiravir (loading dose: 2x1600 mg, 2x600 mg, oral) | Initial Entry                                |
| Nov-16-2020<br>17:34:37<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b>  | Initial Entry                                |
| Nov-13-2020<br>11:47:54<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done  | Initial Entry                                |

5. Start Date:

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Nov-16-2020 17:43:46<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/11/2020 | Initial Entry |
| Nov-16-2020 17:34:37<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b>                | Initial Entry |
| Nov-13-2020 11:47:54<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done    | Initial Entry |

6. Ongoing?

| Date   | Location        | User                | Value  | Reason              |
|--|-----------------|---------------------|--|---------------------|
| Nov-24-2020 13:48:47<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO<br>End Date:<br>Nov/11/2020 | Transcription Error |
| Nov-16-2020 17:43:46<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO<br>End Date:<br>Nov/15/2020 | Initial Entry       |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Deleted, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

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|  |                 |                     |                                |               |
|--|-----------------|---------------------|--------------------------------|---------------|
| Nov-16-2020 17:34:37<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b>             | Initial Entry |
| Nov-13-2020 11:47:54<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

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Generated By: (b) (4)

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1. What is the medication identifier?

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Nov-16-2020 17:46:59<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>2 | Initial Entry |

2. Category:

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-16-2020 17:46:59<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>GENERAL CONCOMITANT MEDICATIONS | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-16-2020 17:46:59<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>NO | Initial Entry |

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

| Date   | Location        | User                         | Value              | Reason   |
|--|-----------------|------------------------------|--------------------|--|
| Dec-08-2020 22:04:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 2: Closed    | Response satisfies query   |
| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)    | Query 2: Answered  | data was entered by mistake.   |
| Dec-04-2020 23:01:06<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)             | Query 2: Opened    | Clin: Only vasopressors are to be recorded on this CRF page. Please review and update CRF or else clarify. |
| Dec-04-2020 22:19:53                         | ACV0PFEINFP6000 | Salim Bouguermouh            | Query 2: Candidate | Clin: Only vasopressors are  |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:55**Form Status:** Data Complete, Deleted, Verified**Site No:** 1217**Site Name:** (1217) Kocaeli University Faculty of Medicine**Subject No:** 12171044**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11**\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\***

|  |   |                           |  |  |
|--|---|---------------------------|--|--|
| (UTC+03:00)<br>Istanbul                            |   | (b) (4)                   |  | to be recorded on this CRF page. Please review and update CRF or else clarify.           |
| Nov-24-2020<br>13:52:17<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>Azithromycin(load ing dose;1x500 mg ,oral)               | Changed Information  |
| Nov-16-2020<br>22:05:17<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle<br>(b) (4)  | Query 1: Closed  | Discrepancy has been closed.   |
| Nov-16-2020<br>19:55:57<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | auto query<br>(autoquery) | Query 1: Answered  | Transcription Error  |
| Nov-16-2020<br>19:55:57<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>Azithromycin(load ing dose;1x500 mg ,1x250 mg,oral)      | Transcription Error  |
| Nov-16-2020<br>19:08:36<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle<br>(b) (4)  | Query 1: Opened  | Spacing:<br>Verbatim Term contains leading, trailing or more than one consecutive space. |
| Nov-16-2020<br>17:46:59<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>Azithromycin (load ing dose; 1x500 m g , 1x250 mg, oral) | Initial Entry  |

**5. Start Date:**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Nov-16-2020 17:46:59<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/14/2020 | Initial Entry |

**6. Ongoing?**

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

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**Form Status:** Data Complete, Deleted, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

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|  |                 |                               |  |                     |
|--|-----------------|-------------------------------|--|---------------------|
| Nov-24-2020 13:52:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b><br>NO<br>End Date:<br><br>Nov/14/2020 | Transcription Error |
| Nov-19-2020 18:34:36<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>NO<br>End Date:<br><br>Nov/16/2020 | New Information     |
| Nov-16-2020 17:46:59<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b><br>YES                                | Initial Entry       |

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1. What is the medication identifier?

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Nov-16-2020 17:48:03<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>3 | Initial Entry |

2. Category:

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-16-2020 17:48:03<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>GENERAL CONCOMITANT MEDICATIONS | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-16-2020 17:48:03<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>NO | Initial Entry |

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

| Date   | Location        | User                         | Value                 | Reason   |
|--|-----------------|------------------------------|-----------------------|--|
| Dec-08-2020 22:04:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 2:<br>Closed    | Response satisfies query   |
| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)    | Query 2:<br>Answered  | data was entered by mistake.   |
| Dec-04-2020 23:01:06<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)             | Query 2:<br>Opened    | Clin: Only vasopressors are to be recorded on this CRF page. Please review and update CRF or else clarify. |
| Dec-04-2020 22:23:19<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 2:<br>Candidate | Clin: Only vasopressors are to be recorded on this CRF page. Please review and update CRF or else clarify. |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Deleted, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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|  |   |                            |  |   |
|--|---|----------------------------|--|---|
| Nov-19-2020<br>18:56:08<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>PRECOR<br>T-LIYO (METHYL<br>PREDNI<br>SOLONE<br>,1x 40 mg<br>, IV) | Transcription Error   |
| Nov-19-2020<br>18:41:09<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>METHYL<br>PREDNI<br>SOLONE<br>(1x 40 mg<br>, IV)                   | Transcription Error   |
| Nov-17-2020<br>16:02:33<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle<br>(b) (4)   | Query 1:<br>Closed   | Discrepancy has been closed.  |
| Nov-17-2020<br>15:34:42<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | auto query<br>(autoquery)  | Query 1:<br>Answered   | New Information   |
| Nov-17-2020<br>15:34:42<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>METHYL<br>PREDNI<br>SOLONE<br>(1x 40 mg<br>, oral )                | New Information   |
| Nov-16-2020<br>20:39:20<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle<br>(b) (4)   | Query 1:<br>Opened   | Clarify PREDNOL (1X 40 MG, ORAL ) as follows...Multiple formulations available. Please clarify if reporting PREDNOL [DESONIDE] (1X 40 MG, ORAL ) or PREDNOL [METHYLPREDNISOLONE] (1X 40 MG, ORAL ) or other and update the term. Thank you. |
| Nov-16-2020<br>17:48:03                            | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)        | <b>Data Entry:</b>   | Initial Entry   |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Deleted, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

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|                         |  |  |                                  |  |
|-------------------------|--|--|----------------------------------|--|
| (UTC+03:00)<br>Istanbul |  |  | prednol (1<br>x 40 mg,<br>oral ) |  |
|-------------------------|--|--|----------------------------------|--|

**5. Start Date:**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Nov-16-2020 17:48:03<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <u>Data Entry:</u><br>Nov/15/2020 | Initial Entry |

**6. Ongoing?**

| Date   | Location        | User                          | Value  | Reason          |
|--|-----------------|-------------------------------|--|-----------------|
| Nov-19-2020 18:41:32<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <u>Data Entry:</u><br>NO<br>End Date:<br>Nov/16/2020 | New Information |
| Nov-16-2020 17:48:03<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <u>Data Entry:</u><br>YES                            | Initial Entry   |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

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Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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1. What is the medication identifier?

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Nov-18-2020 16:06:52<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>4 | Initial Entry |

2. Category:

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-18-2020 16:06:52<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>GENERAL CONCOMITANT MEDICATIONS | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-18-2020 16:06:52<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>NO | Initial Entry |

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

| Date   | Location        | User                         | Value              | Reason   |
|--|-----------------|------------------------------|--------------------|--|
| Dec-08-2020 22:04:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 1: Closed    | Response satisfies query   |
| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)    | Query 1: Answered  | data was entered by mistake.   |
| Dec-04-2020 23:01:06<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)             | Query 1: Opened    | Clin: Only vasopressors are to be recorded on this CRF page. Please review and update CRF or else clarify. |
| Dec-04-2020 22:24:50<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 1: Candidate | Clin: Only vasopressors are to be recorded on this CRF page. Please review and update CRF or else clarify. |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

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Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

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Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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|  |                 |                            |  |                     |
|--|-----------------|----------------------------|--|---------------------|
| Nov-19-2020 18:57:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>LANSAZOL (Lansoprazole, 30 mg<br>, 1x1 oral) | Transcription Error |
| Nov-18-2020 16:10:11<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br>Lansoprazol 30 mg (1x1 oral)                 | Changed Information |
| Nov-18-2020 16:06:52<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br>lansazol 30 mg (1x1 oral)                    | Initial Entry       |

5. Start Date:

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Nov-18-2020 16:06:52<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/11/2020 | Initial Entry |

6. Ongoing?

| Date   | Location        | User                       | Value  | Reason              |
|--|-----------------|----------------------------|--|---------------------|
| Nov-19-2020 18:43:55<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>NO<br>End Date:<br>Nov/16/2020 | Transcription Error |
| Nov-18-2020 16:10:46<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br>NO<br>End Date:<br>Nov/17/2020 | Initial Entry       |

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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Form Status: Data Complete, Deleted, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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1. What is the medication identifier?

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Nov-18-2020 16:16:22<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>5 | Initial Entry |

2. Category:

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-18-2020 16:16:22<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>GENERAL CONCOMITANT MEDICATIONS | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-18-2020 16:16:22<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>NO | Initial Entry |

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

| Date   | Location        | User                         | Value              | Reason   |
|--|-----------------|------------------------------|--------------------|--|
| Dec-08-2020 22:04:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 2: Closed    | Response satisfies query   |
| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)    | Query 2: Answered  | data was entered by mistake.   |
| Dec-04-2020 23:01:06<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)             | Query 2: Opened    | Clin: Only vasopressors are to be recorded on this CRF page. Please review and update CRF or else clarify. |
| Dec-04-2020 22:26:11<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 2: Candidate | Clin: Only vasopressors are to be recorded on this CRF page. Please review and update CRF                  |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

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Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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|  |   |                            |  | or else clarify.   |
|--|---|----------------------------|--|--|
| Nov-19-2020<br>20:57:14<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle<br>(b) (4)   | Query 1: Closed  | Discrepancy has been closed.   |
| Nov-19-2020<br>18:58:35<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>MUSCORIL (THIOLCH ICOSIDE Injection, 4 mg/2 mg, IV, 1x1) | Transcription Error  |
| Nov-19-2020<br>18:50:10<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>THIOLCH ICOSIDE Injection, 4 mg/2 mg, IV, 1x1            | Transcription Error  |
| Nov-19-2020<br>18:49:51<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | auto query<br>(autoquery)  | Query 1: Answered  | Changed Information  |
| Nov-19-2020<br>18:49:51<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>THIOLCH ICOSIDE Injection 4 mg/2 mg, IV                  | Changed Information  |
| Nov-18-2020<br>18:27:23<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle<br>(b) (4)   | Query 1: Opened  | Clarify<br>TIYOKOLSIKOSID 4 MG /C2 ML 6AMP (1X1 INTRAMUSCULER) as follows...Should the spelling be THIOLCHICOSIDE 4 MG /C2 ML 6AMP (1X1 INTRAMUSCULER)? If so, update the verbatim term as such. Otherwise clarify and update the term as appropriate or provide reference/label. Thank you. |

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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|  |                 |                     |  |               |
|--|-----------------|---------------------|--|---------------|
| Nov-18-2020<br>16:16:22<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Tiyokolsikosi<br>d 4 mg /c2 M<br>L 6AMP (1x1<br>intramusculer) | Initial Entry |
|--|-----------------|---------------------|--|---------------|

5. Start Date:

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Nov-18-2020 16:16:22<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/11/2020 | Initial Entry |

6. Ongoing?

| Date   | Location        | User                          | Value  | Reason              |
|--|-----------------|-------------------------------|--|---------------------|
| Nov-19-2020 18:50:19<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>NO<br>End Date:<br>Nov/16/2020 | Transcription Error |
| Nov-18-2020 16:16:22<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b><br>NO<br>End Date:<br>Nov/17/2020 | Initial Entry       |

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Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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Site No: 1217

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Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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1. What is the medication identifier?

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Nov-18-2020 16:19:35<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>6 | Initial Entry |

2. Category:

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-18-2020 16:19:35<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>GENERAL CONCOMITANT MEDICATIONS | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-18-2020 16:19:35<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>NO | Initial Entry |

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

| Date   | Location        | User                         | Value              | Reason   |
|--|-----------------|------------------------------|--------------------|--|
| Dec-08-2020 22:04:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 2: Closed    | Response satisfies query   |
| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)    | Query 2: Answered  | data was entered by mistake.   |
| Dec-04-2020 23:01:06<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)             | Query 2: Opened    | Clin: Only vasopressors are to be recorded on this CRF page. Please review and update CRF or else clarify. |
| Dec-04-2020 22:27:41<br>(UTC+03:00)          | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 2: Candidate | Clin: Only vasopressors are to be recorded on this CRF   |

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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|  |   |                            |  |  |
|--|---|----------------------------|--|--|
| Istanbul   |   |                            |  | page. Please review and update CRF or else clarify.  |
| Nov-24-2020<br>14:05:34<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br>OKSAPAR (E<br>NOXAPARIN<br>SODIUM, 1x0.<br>6ml,subcutaneo<br>us)           | Changed Information  |
| Nov-24-2020<br>11:39:32<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br>OKSAPAR (E<br>NOXAPARIN<br>SODIUM, 60m<br>g/0.6ml,subcuta<br>neous, 1x0.6) | Changed Information  |
| Nov-19-2020<br>20:57:37<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle<br>(b) (4)   | Query 1: Close<br>d  | Discrepancy has been<br>closed.  |
| Nov-19-2020<br>18:54:20<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | auto query<br>(autoquery)  | Query 1: Answ<br>ered  | Changed Information  |
| Nov-19-2020<br>18:54:20<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>OKSAPAR (E<br>NOXAPARIN<br>SODIUM, 60m<br>g/0.6ml, IV, 1x<br>0.6)          | Changed Information  |
| Nov-18-2020<br>18:27:45<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle<br>(b) (4)   | Query 1: Opene<br>d  | Clarify<br>ENOKSAPARIN<br>SODIUM (60 MG (1<br>X 0,6 SUBCUTAN )<br>as follows...Should<br>the spelling be<br>ENOXAPARIN<br>SODIUM (60MG (1<br>X 0,6<br>SUBCUTANEOUS)?<br>If so, update the<br>verbatim term as<br>such. Otherwise<br>clarify and update the<br>term as appropriate or |

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Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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|  |                 |                     |  |                                     |
|--|-----------------|---------------------|--|-------------------------------------|
|  |                 |                     |  | provide reference/label. Thank you. |
| Nov-18-2020<br>16:28:28<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Enoksaparin sodium (60 MG ( 1 X 0,6 subcutan ) | Changed Information                 |
| Nov-18-2020<br>16:19:35<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Enoksaparin sodium (60 MG ( 1 X 0,6 subcutan ) | Initial Entry                       |

5. Start Date:

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Nov-18-2020 16:19:35<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/11/2020 | Initial Entry |

6. Ongoing?

| Date   | Location        | User                       | Value  | Reason              |
|--|-----------------|----------------------------|--|---------------------|
| Nov-24-2020 14:05:53<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)           | <b>Data Entry:</b><br>NO<br>End Date:<br>Nov/19/2020 | Changed Information |
| Nov-19-2020 19:00:12<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>NO<br>End Date:<br>Nov/16/2020 | New Information     |
| Nov-18-2020 16:19:35<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br>YES                            | Initial Entry       |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Deleted, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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1. What is the medication identifier?

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Nov-18-2020 16:24:12<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>7 | Initial Entry |

2. Category:

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-18-2020 16:24:12<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>GENERAL CONCOMITANT MEDICATIONS | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-18-2020 16:24:12<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>NO | Initial Entry |

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

| Date   | Location                                  | User                        | Value  | Reason                       |
|--|---|-----------------------------|--|------------------------------|
| Nov-24-2020 11:37:57<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)         | <u>Data Entry:</u><br>OKSAPAR (ENOXA PARIN SODIUM, 1x 0.6 ml,subcutaneous) | Changed Information          |
| Nov-19-2020 20:57:59<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS<br>Oracle<br>(b) (4) | Query 1: Closed  | Discrepancy has been closed. |
| Nov-19-2020 19:05:26<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000                           | auto query<br>(autoquery)   | Query 1: Answered  | Changed Information          |
| Nov-19-2020 19:05:26<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000                           | Binnur Yildirim<br>(b) (4)  | <u>Data Entry:</u><br>OKSAPAR (ENOXA PARIN SODIUM, 1x 0.6 ml,supcutaneous) | Changed Information          |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Deleted, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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|  |   |                             |   |   |
|--|---|-----------------------------|---|---|
| Nov-18-2020<br>17:32:07<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS<br>Oracle<br>(b) (4) | Query 1: Opened   | Spacing:<br>Verbatim Term<br>contains leading,<br>trailing or more<br>than one<br>consecutive<br>space. |
| Nov-18-2020<br>16:24:12<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)         | <b>Data Entry:</b><br>%0,9 Isotonic sodiu<br>m chlorur 100 mL | Initial Entry   |

5. Start Date:

| Date   | Location        | User                          | Value                             | Reason              |
|--|-----------------|-------------------------------|-----------------------------------|---------------------|
| Nov-19-2020 19:06:15<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Nov/17/2020 | Transcription Error |
| Nov-18-2020 16:24:12<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b><br>Nov/11/2020 | Initial Entry       |

6. Ongoing?

| Date   | Location        | User                          | Value  | Reason              |
|--|-----------------|-------------------------------|--|---------------------|
| Nov-23-2020 16:25:25<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>NO<br>End Date:<br>Nov/19/2020 | New Information     |
| Nov-19-2020 19:05:57<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>YES                            | Transcription Error |
| Nov-18-2020 16:24:12<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)           | <b>Data Entry:</b><br>NO<br>End Date:<br>Nov/15/2020 | Initial Entry       |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Deleted, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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1. What is the medication identifier?

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Nov-18-2020 16:27:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>8 | Initial Entry |

2. Category:

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-18-2020 16:27:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>GENERAL CONCOMITANT MEDICATIONS | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-18-2020 16:27:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>NO | Initial Entry |

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

| Date   | Location        | User                         | Value              | Reason   |
|--|-----------------|------------------------------|--------------------|--|
| Dec-08-2020 22:04:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 2: Closed    | Response satisfies query   |
| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)    | Query 2: Answered  | data was entered by mistake.   |
| Dec-04-2020 23:01:06<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)             | Query 2: Opened    | Clin: Only vasopressors are to be recorded on this CRF page. Please review and update CRF or else clarify. |
| Dec-04-2020 22:29:44<br>(UTC+03:00)          | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 2: Candidate | Clin: Only vasopressors are to be recorded on this CRF   |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Deleted, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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|   |   |                         |  |  |
|---|---|-------------------------|--|--|
| Istanbul                                  |   |                         |  | page. Please review and update CRF or else clarify.  |
| Nov-19-2020 20:58:21 (UTC+03:00) Istanbul | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4)   | Query 1: Closed  | Discrepancy has been closed.   |
| Nov-19-2020 19:09:27 (UTC+03:00) Istanbul | ACV0PFEINFP6000                           | auto query (autoquery)  | Query 1: Answered  | Changed Information  |
| Nov-19-2020 19:09:27 (UTC+03:00) Istanbul | ACV0PFEINFP6000                           | Binnur Yildirim (b) (4) | <b>Data Entry:</b> DEXAMETHASONE (6 mg, 1x1, oral)       | Changed Information  |
| Nov-18-2020 18:28:06 (UTC+03:00) Istanbul | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4)   | Query 1: Opened  | Clarify DEKSAMETAZON 6 MG ( 1 X 6 MG , ORAL ) as follows...Should the spelling be DEXAMETHASONE 6 MG ( 1 X 6 MG , ORAL )? If so, update the verbatim term as such. Otherwise clarify and update the term as appropriate or provide reference/label. Thank you. |
| Nov-18-2020 16:27:29 (UTC+03:00) Istanbul | ACV0PFEINFP6000                           | (b) (4), (b) (6)        | <b>Data Entry:</b> deksametazon 6 mg ( 1 x 6 mg , oral ) | Initial Entry  |

5. Start Date:

| Date                                      | Location        | User                    | Value                          | Reason              |
|---|-----------------|-------------------------|--------------------------------|---------------------|
| Nov-19-2020 19:08:23 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim (b) (4) | <b>Data Entry:</b> Nov/17/2020 | Transcription Error |
| Nov-18-2020 16:27:29 (UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)        | <b>Data Entry:</b> Nov/11/2020 | Initial Entry       |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Deleted, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

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**6. Ongoing?**

| Date   | Location        | User                | Value                     | Reason        |
|--|-----------------|---------------------|---------------------------|---------------|
| Nov-18-2020 16:27:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Deleted, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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1. What is the medication identifier?

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Nov-19-2020 19:07:37<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>9 | Initial Entry |

2. Category:

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-19-2020 19:07:37<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>GENERAL CONCOMITANT MEDICATIONS | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-19-2020 19:07:37<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>NO | Initial Entry |

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

| Date   | Location        | User                         | Value              | Reason   |
|--|-----------------|------------------------------|--------------------|--|
| Dec-08-2020 22:04:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 1: Closed    | Response satisfies query   |
| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)    | Query 1: Answered  | data was entered by mistake.   |
| Dec-04-2020 23:01:06<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)             | Query 1: Opened    | Clin: Only vasopressors are to be recorded on this CRF page. Please review and update CRF or else clarify. |
| Dec-04-2020 22:33:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 1: Candidate | Clin: Only vasopressors are to be recorded on this CRF page. Please review and update CRF or else clarify. |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Deleted, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

|  |                 |                            |  |               |
|--|-----------------|----------------------------|--|---------------|
| Nov-19-2020 19:07:37<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Azithromycin (1x250 mg,oral) | Initial Entry |
|--|-----------------|----------------------------|--|---------------|

5. Start Date:

| Date   | Location        | User                       | Value                             | Reason        |
|--|-----------------|----------------------------|-----------------------------------|---------------|
| Nov-19-2020 19:07:37<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Nov/17/2020 | Initial Entry |

6. Ongoing?

| Date   | Location        | User                       | Value  | Reason          |
|--|-----------------|----------------------------|--|-----------------|
| Nov-23-2020 16:26:17<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>NO<br>End Date:<br>Nov/19/2020 | New Information |
| Nov-19-2020 19:07:37<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>YES                            | Initial Entry   |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Deleted, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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1. What is the medication identifier?

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-23-2020 16:28:47<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>10 | Initial Entry |

2. Category:

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-23-2020 16:28:47<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>GENERAL CONCOMITANT MEDICATIONS | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-23-2020 16:28:47<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>NO | Initial Entry |

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

| Date   | Location        | User                         | Value              | Reason   |
|--|-----------------|------------------------------|--------------------|--|
| Dec-08-2020 22:04:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 1: Closed    | Response satisfies query   |
| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)    | Query 1: Answered  | data was entered by mistake.   |
| Dec-04-2020 23:01:06<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)             | Query 1: Opened    | Clin: Only vasopressors are to be recorded on this CRF page. Please review and update CRF or else clarify. |
| Dec-04-2020 22:34:24<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 1: Candidate | Clin: Only vasopressors are to be recorded on this CRF page. Please review and update CRF or else clarify. |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Deleted, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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|  |                 |                            |  |                     |
|--|-----------------|----------------------------|--|---------------------|
| Nov-24-2020 11:45:13<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br>CLEXANE(ENOXAPARIN SODI<br>UM 1x0.8 mg,subcutaneous) | Changed Information |
| Nov-24-2020 11:40:18<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br>CLEXANE(ENOXAPARIN SODI<br>UM 1X0.8 mg,subcutaneous) | Changed Information |
| Nov-23-2020 16:28:47<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>CLEXANE(ENOXAPARIN SODI<br>UM 1X0.8 mg IV)           | Initial Entry       |

5. Start Date:

| Date   | Location        | User                          | Value                             | Reason        |
|--|-----------------|-------------------------------|-----------------------------------|---------------|
| Nov-23-2020 16:28:47<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Nov/20/2020 | Initial Entry |

6. Ongoing?

| Date   | Location        | User                          | Value                     | Reason        |
|--|-----------------|-------------------------------|---------------------------|---------------|
| Nov-23-2020 16:28:47<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Deleted, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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1. What is the medication identifier?

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-23-2020 16:54:22<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>11 | Initial Entry |

2. Category:

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-23-2020 16:54:22<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>GENERAL CONCOMITANT MEDICATIONS | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-23-2020 16:54:22<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>NO | Initial Entry |

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

| Date   | Location        | User                         | Value              | Reason   |
|--|-----------------|------------------------------|--------------------|--|
| Dec-08-2020 22:04:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 1: Closed    | Response satisfies query   |
| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)    | Query 1: Answered  | data was entered by mistake.   |
| Dec-04-2020 23:01:06<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)             | Query 1: Opened    | Clin: Only vasopressors are to be recorded on this CRF page. Please review and update CRF or else clarify. |
| Dec-04-2020 22:35:03<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 1: Candidate | Clin: Only vasopressors are to be recorded on this CRF page. Please review and update CRF or else clarify. |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Deleted, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

|  |                 |                            |   |               |
|--|-----------------|----------------------------|---|---------------|
| Nov-23-2020 16:54:22<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Teicoplanin (1x400 mg IV) | Initial Entry |
|--|-----------------|----------------------------|---|---------------|

**5. Start Date:**

| Date   | Location        | User                       | Value                             | Reason        |
|--|-----------------|----------------------------|-----------------------------------|---------------|
| Nov-23-2020 16:54:22<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Nov/20/2020 | Initial Entry |

**6. Ongoing?**

| Date   | Location        | User                       | Value  | Reason              |
|--|-----------------|----------------------------|--|---------------------|
| Dec-03-2020 13:55:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>NO<br>End Date:<br>Nov/29/2020 | Changed Information |
| Nov-23-2020 16:54:22<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>YES                            | Initial Entry       |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Deleted, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

[Back to Form](#)

1. What is the medication identifier?

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-23-2020 16:57:12<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>12 | Initial Entry |

2. Category:

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-23-2020 16:57:12<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>GENERAL CONCOMITANT MEDICATIONS | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-23-2020 16:57:12<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>NO | Initial Entry |

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

| Date   | Location        | User                         | Value              | Reason   |
|--|-----------------|------------------------------|--------------------|--|
| Dec-08-2020 22:04:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 1: Closed    | Response satisfies query   |
| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)    | Query 1: Answered  | data was entered by mistake.   |
| Dec-04-2020 23:01:06<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)             | Query 1: Opened    | Clin: Only vasopressors are to be recorded on this CRF page. Please review and update CRF or else clarify. |
| Dec-04-2020 22:35:17<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 1: Candidate | Clin: Only vasopressors are to be recorded on this CRF page. Please review and update CRF or else clarify. |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Deleted, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

|  |                 |                            |   |                     |
|--|-----------------|----------------------------|---|---------------------|
| Nov-24-2020 11:47:09<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br>Piperacillin - tazobactam (3x4.5 g/d ay IV) | Changed Information |
| Nov-23-2020 16:57:12<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Piperacillin - tazobactam (3x4.5 g I V)     | Initial Entry       |

**5. Start Date:**

| Date   | Location        | User                       | Value                             | Reason        |
|--|-----------------|----------------------------|-----------------------------------|---------------|
| Nov-23-2020 16:57:12<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Nov/20/2020 | Initial Entry |

**6. Ongoing?**

| Date   | Location        | User                       | Value  | Reason              |
|--|-----------------|----------------------------|--|---------------------|
| Dec-03-2020 13:56:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>NO<br>End Date:<br>Nov/29/2020 | Changed Information |
| Nov-23-2020 16:57:12<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>YES                            | Initial Entry       |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Deleted, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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1. What is the medication identifier?

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-23-2020 16:59:48<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>13 | Initial Entry |

2. Category:

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-23-2020 16:59:48<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>GENERAL CONCOMITANT MEDICATIONS | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-23-2020 16:59:48<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>NO | Initial Entry |

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

| Date   | Location        | User                         | Value              | Reason   |
|--|-----------------|------------------------------|--------------------|--|
| Dec-08-2020 22:04:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 2: Closed    | Response satisfies query   |
| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)    | Query 2: Answered  | data was entered by mistake.   |
| Dec-04-2020 23:01:06<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)             | Query 2: Opened    | Clin: Only vasopressors are to be recorded on this CRF page. Please review and update CRF or else clarify. |
| Dec-04-2020 22:36:22<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 2: Candidate | Clin: Only vasopressors are to be recorded on this CRF page. Please review and update CRF or else clarify. |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Deleted, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

|  |                 |                              |   |  |
|--|-----------------|------------------------------|---|--|
| Dec-04-2020 22:36:06<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 1: Closed                                 | Response satisfies query   |
| Dec-04-2020 22:35:52<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 1: Opened                                 | Clin: Only vasopressors are to be recorded on this CRF page. Please review and update CRF or else clarify. |
| Nov-23-2020 16:59:48<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4)   | <b>Data Entry:</b><br>Tocilizumab (1x400 mg IV) | Initial Entry  |

5. Start Date:

| Date   | Location        | User                       | Value                             | Reason        |
|--|-----------------|----------------------------|-----------------------------------|---------------|
| Nov-23-2020 16:59:48<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Nov/20/2020 | Initial Entry |

6. Ongoing?

| Date   | Location        | User                       | Value  | Reason          |
|--|-----------------|----------------------------|--|-----------------|
| Nov-24-2020 11:53:03<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br>NO<br>End Date:<br>Nov/22/2020 | New Information |
| Nov-23-2020 16:59:48<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>YES                            | Initial Entry   |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

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Form Status: Data Complete, Deleted, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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1. What is the medication identifier?

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-24-2020 11:57:06<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>14 | Initial Entry |

2. Category:

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-24-2020 11:57:06<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>GENERAL CONCOMITANT MEDICATIONS | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-24-2020 11:57:06<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>NO | Initial Entry |

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

| Date   | Location        | User                         | Value             | Reason  |
|--|-----------------|------------------------------|-------------------|---|
| Dec-08-2020 22:04:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 2: Closed   | Response satisfies query  |
| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)    | Query 2: Answered | data was entered by mistake.  |
| Dec-04-2020 23:03:26<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)             | Query 2: Opened   | Clin: Only vasopressors are to be recorded on this CRF page. Please should be added to the respiratory treatment CRF form. Please review and update |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Deleted, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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|  |   |                              |  | CRF or else clarify.  |
|--|---|------------------------------|--|---|
| Dec-04-2020<br>22:38:46<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | Salim Bouguermouh<br>(b) (4) | Query 2: Candidate                           | Clin: Only vasopressors are to be recorded on this CRF page. Please should be added to the respiratory treatment CRF form. Please review and update CRF or else clarify.  |
| Nov-25-2020<br>13:36:41<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle<br>(b) (4)     | Query 1: Closed                              | Discrepancy has been closed.  |
| Nov-25-2020<br>11:32:01<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | auto query (autoquery)       | Query 1: Answered                            | Changed Information   |
| Nov-25-2020<br>11:32:01<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)          | <b>Data Entry:</b><br>Oxygen mask (12 L/MIN) | Changed Information   |
| Nov-24-2020<br>16:10:30<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle<br>(b) (4)     | Query 1: Opened                              | Clarify NASAL OXYGEN MASK (12 LT/MIN) as follows...Should the spelling be NASAL OXYGEN MASK (12 L/MIN)? If so, update the verbatim term as such. Otherwise clarify and expand the abbreviation LT and update the term as appropriate or provide reference/label. Thank you. |

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

|  |                 |                     |   |                 |
|--|-----------------|---------------------|---|-----------------|
| Nov-24-2020<br>13:54:26<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nasal oxygen mask (12 Lt/min) | New Information |
| Nov-24-2020<br>11:57:06<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nasal oxygen 12 Lt/min        | Initial Entry   |

5. Start Date:

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Nov-24-2020 11:57:06<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/20/2020 | Initial Entry |

6. Ongoing?

| Date   | Location        | User                | Value  | Reason              |
|--|-----------------|---------------------|--|---------------------|
| Nov-24-2020 14:37:53<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO<br>End Date:<br>Nov/21/2020 | Changed Information |
| Nov-24-2020 11:57:06<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES                            | Initial Entry       |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

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Form Status: Data Complete, Deleted, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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1. What is the medication identifier?

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-24-2020 13:49:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>15 | Initial Entry |

2. Category:

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-24-2020 13:49:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>GENERAL CONCOMITANT MEDICATIONS | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-24-2020 13:49:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>NO | Initial Entry |

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

| Date   | Location        | User                         | Value              | Reason   |
|--|-----------------|------------------------------|--------------------|--|
| Dec-08-2020 22:04:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 1: Closed    | Response satisfies query   |
| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)    | Query 1: Answered  | data was entered by mistake.   |
| Dec-04-2020 23:01:06<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)             | Query 1: Opened    | Clin: Only vasopressors are to be recorded on this CRF page. Please review and update CRF or else clarify. |
| Dec-04-2020 22:46:09<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 1: Candidate | Clin: Only vasopressors are to be recorded on this CRF page. Please review and update CRF or else clarify. |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Deleted, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

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|  |                 |                     |  |               |
|--|-----------------|---------------------|--|---------------|
| Nov-24-2020 13:49:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Favipiravir(2x600 mg,oral) | Initial Entry |
|--|-----------------|---------------------|--|---------------|

**5. Start Date:**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Nov-24-2020 13:49:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/12/2020 | Initial Entry |

**6. Ongoing?**

| Date   | Location        | User                | Value  | Reason          |
|--|-----------------|---------------------|--|-----------------|
| Nov-24-2020 13:49:39<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO<br>End Date:<br>Nov/15/2020 | New Information |
| Nov-24-2020 13:49:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES                            | Initial Entry   |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

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Form Status: Data Complete, Deleted, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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1. What is the medication identifier?

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-24-2020 13:53:06<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>16 | Initial Entry |

2. Category:

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-24-2020 13:53:06<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>GENERAL CONCOMITANT MEDICATIONS | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-24-2020 13:53:06<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>NO | Initial Entry |

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

| Date   | Location        | User                         | Value              | Reason   |
|--|-----------------|------------------------------|--------------------|--|
| Dec-08-2020 22:04:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 1: Closed    | Response satisfies query   |
| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)    | Query 1: Answered  | data was entered by mistake.   |
| Dec-04-2020 23:01:06<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)             | Query 1: Opened    | Clin: Only vasopressors are to be recorded on this CRF page. Please review and update CRF or else clarify. |
| Dec-04-2020 22:46:27<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 1: Candidate | Clin: Only vasopressors are to be recorded on this CRF page. Please review and update CRF or else clarify. |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Deleted, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

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|  |                 |                     |   |               |
|--|-----------------|---------------------|---|---------------|
| Nov-24-2020 13:53:06<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Azithromycin(1x250 mg,oral) | Initial Entry |
|--|-----------------|---------------------|---|---------------|

**5. Start Date:**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Nov-24-2020 13:53:06<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/15/2020 | Initial Entry |

**6. Ongoing?**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-24-2020 13:53:06<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO<br>End Date:<br>Nov/16/2020 | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Deleted, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

[Back to Form](#)

1. What is the medication identifier?

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-24-2020 14:39:26<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>17 | Initial Entry |

2. Category:

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-24-2020 14:39:26<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>GENERAL CONCOMITANT MEDICATIONS | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-24-2020 14:39:26<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>NO | Initial Entry |

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

| Date   | Location        | User                         | Value              | Reason   |
|--|-----------------|------------------------------|--------------------|--|
| Dec-08-2020 22:04:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 1: Closed    | Response satisfies query   |
| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)    | Query 1: Answered  | data was entered by mistake.   |
| Dec-04-2020 23:03:56<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)             | Query 1: Opened    | Clin: Only vasopressors are to be recorded on this CRF page. Please should be added to the respiratory treatment CRF form. Please review and update CRF or else clarify. |
| Dec-04-2020 22:46:52<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 1: Candidate | Clin: Only vasopressors are to be recorded on this CRF   |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Deleted, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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|  |                 |                     |  |   |
|--|-----------------|---------------------|--|---|
|  |                 |                     |  | page. Please should be added to the respiratory treatment CRF form. Please review and update CRF or else clarify. |
| Nov-25-2020 11:32:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nasal Cannula oxygen (6 L/MIN) | Changed Information   |
| Nov-24-2020 14:39:26<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nasal Cannula oxygen (6Lt/min) | Initial Entry   |

5. Start Date:

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Nov-24-2020 14:39:26<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/22/2020 | Initial Entry |

6. Ongoing?

| Date   | Location        | User                       | Value  | Reason              |
|--|-----------------|----------------------------|--|---------------------|
| Dec-03-2020 13:58:12<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>NO<br>End Date:<br>Nov/28/2020 | Changed Information |
| Nov-24-2020 14:39:26<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br>YES                            | Initial Entry       |

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Deleted, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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1. What is the medication identifier?

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-26-2020 11:53:16<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>18 | Initial Entry |

2. Category:

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Nov-26-2020 11:53:16<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>GENERAL CONCOMITANT MEDICATIONS | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Nov-26-2020 11:53:16<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>NO | Initial Entry |

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

| Date   | Location        | User                         | Value              | Reason   |
|--|-----------------|------------------------------|--------------------|--|
| Dec-08-2020 22:04:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 1: Closed    | Response satisfies query   |
| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)    | Query 1: Answered  | data was entered by mistake.   |
| Dec-04-2020 23:01:06<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)             | Query 1: Opened    | Clin: Only vasopressors are to be recorded on this CRF page. Please review and update CRF or else clarify. |
| Dec-04-2020 22:47:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 1: Candidate | Clin: Only vasopressors are to be recorded on this CRF page. Please review and update CRF or else clarify. |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Deleted, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

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|  |                 |                     |   |               |
|--|-----------------|---------------------|---|---------------|
| Nov-26-2020 11:53:16<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Teicoplanin (loading dose, 2x400 mg IV) | Initial Entry |
|--|-----------------|---------------------|---|---------------|

**5. Start Date:**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Nov-26-2020 11:53:16<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/20/2020 | Initial Entry |

**6. Ongoing?**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Nov-26-2020 11:53:16<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO<br>End Date:<br>Nov/20/2020 | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Deleted, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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1. What is the medication identifier?

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Dec-03-2020 14:01:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>19 | Initial Entry |

2. Category:

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Dec-03-2020 14:01:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>GENERAL CONCOMITANT MEDICATIONS | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Dec-03-2020 14:01:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>NO | Initial Entry |

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

| Date   | Location        | User                         | Value              | Reason   |
|--|-----------------|------------------------------|--------------------|--|
| Dec-08-2020 22:04:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 1: Closed    | Response satisfies query   |
| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)    | Query 1: Answered  | data was entered by mistake.   |
| Dec-04-2020 23:01:06<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)             | Query 1: Opened    | Clin: Only vasopressors are to be recorded on this CRF page. Please review and update CRF or else clarify. |
| Dec-04-2020 22:49:17<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 1: Candidate | Clin: Only vasopressors are to be recorded on this CRF page. Please review and update CRF or else clarify. |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Deleted, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

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|  |                 |                            |  |               |
|--|-----------------|----------------------------|--|---------------|
| Dec-03-2020 14:01:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Lansazol (lansoprazole, 30 mg, 1x1 oral) | Initial Entry |
|--|-----------------|----------------------------|--|---------------|

**5. Start Date:**

| Date   | Location        | User                       | Value                             | Reason        |
|--|-----------------|----------------------------|-----------------------------------|---------------|
| Dec-03-2020 14:01:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Nov/20/2020 | Initial Entry |

**6. Ongoing?**

| Date   | Location        | User                       | Value                     | Reason        |
|--|-----------------|----------------------------|---------------------------|---------------|
| Dec-03-2020 14:01:34<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>YES | Initial Entry |

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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Deleted, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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1. What is the medication identifier?

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Dec-03-2020 14:03:37<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>20 | Initial Entry |

2. Category:

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Dec-03-2020 14:03:37<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>GENERAL CONCOMITANT MEDICATIONS | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Dec-03-2020 14:03:37<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <u>Data Entry:</u><br>NO | Initial Entry |

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

| Date   | Location        | User                         | Value              | Reason   |
|--|-----------------|------------------------------|--------------------|--|
| Dec-08-2020 22:04:51<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 1: Closed    | Response satisfies query   |
| Dec-07-2020 10:51:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)    | Query 1: Answered  | data was entered by mistake.   |
| Dec-04-2020 22:59:31<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)             | Query 1: Opened    | Clin: Only vasopressors are to be recorded on this CRF page. Please review and update CRF or else clarify. |
| Dec-04-2020 22:50:13<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Salim Bouguermouh<br>(b) (4) | Query 1: Candidate | Clin: Only vasopressors are to be recorded on this CRF page. Please review and update CRF or else clarify. |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Deleted, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

|  |                 |                            |   |               |
|--|-----------------|----------------------------|---|---------------|
| Dec-03-2020 14:03:37<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Seralin (sertraline, 50 mg, 1x1 oral) | Initial Entry |
|--|-----------------|----------------------------|---|---------------|

**5. Start Date:**

| Date   | Location        | User                       | Value                             | Reason        |
|--|-----------------|----------------------------|-----------------------------------|---------------|
| Dec-03-2020 14:03:37<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Nov/20/2020 | Initial Entry |

**6. Ongoing?**

| Date   | Location        | User                       | Value  | Reason        |
|--|-----------------|----------------------------|--|---------------|
| Dec-03-2020 14:03:37<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>NO<br>End Date:<br>Nov/29/2020 | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** IMAGING - Audit Trail

**Form Version:** 06-Jul-2020 21:53

**Form Status:**

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Date   | Location        | User                | Value        | Reason |
|--|-----------------|---------------------|--------------|--------|
| Nov-16-2020 17:33:47<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Form Created |        |

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Date of Assessment:**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Nov-16-2020 17:33:47<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/14/2020 | Initial Entry |
| Nov-16-2020 17:28:26<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b>                | Initial Entry |
| Nov-13-2020 11:47:27<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done    | Initial Entry |

**2. Location of Assessment:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Nov-16-2020 17:33:47<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>CHEST    | Initial Entry |
| Nov-16-2020 17:28:26<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b>             | Initial Entry |
| Nov-13-2020 11:47:27<br>(UTC+03:00) Istanbul | 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        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Nov-16-2020 17:33:47<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>CT SCAN  | Initial Entry |
| Nov-16-2020 17:28:26<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b>             | Initial Entry |
| Nov-13-2020 11:47:27<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**4. Assessment:**

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|  |                 |                     |  |                     |
|--|-----------------|---------------------|--|---------------------|
| Nov-16-2020 19:52:42<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>ABNORMAL<br><i>If abnormal, specify findings:</i><br><br>Report result: COVID-19 category 2 ; prevalent peripheral ground glass density of the bilateral lung.                               | Transcription Error |
| Nov-16-2020 17:44:46<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>ABNORMAL<br><i>If abnormal, specify findings:</i><br><br>The report result is related to the COVID-19 disease; prevalent peripheral ground glass densities of the bilateral lung, category 2 | New Information     |
| Nov-16-2020 17:33:47<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>ABNORMAL<br><i>If abnormal, specify findings:</i><br><br>The report result is related to the COVID-19 disease; prevalent peripheral ground glass densities of the bilateral lung.            | Initial Entry       |
| Nov-16-2020 17:28:26<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b>   | Initial Entry       |
| Nov-13-2020 11:47:27<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done   | Initial Entry       |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled Visit on Dec/10/2020 **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:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

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**1. Date of Visit**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Dec-10-2020 18:38:24<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Dec/10/2020 | Initial Entry |

**3. COVID-19 Illness Visit:**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Dec-10-2020 18:38:24<br>(UTC+03:00) Istanbul | 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 Dec/10/2020**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1217**Site Name:** (1217) Kocaeli University Faculty of Medicine**Subject No:** 12171044**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:11[Back to Form](#)**1. Data Origin**

| Date   | Location        | User                    | Value                      | Reason        |
|--|-----------------|-------------------------|----------------------------|---------------|
| Dec-10-2020 18:38:44<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date   | Location        | User                    | Value                       | Reason        |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Dec-10-2020 18:38:44<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date   | Location        | User                      | Value   | Reason   |
|--|-----------------|---------------------------|---|--|
| Dec-10-2020 18:39:05<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted  | Close Auto Query   |
| Dec-10-2020 18:38:44<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate  | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Dec-10-2020 18:38:44<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(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-10-2020 18:39:05<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Sample ID: BR511S | Initial Entry |

**5.a Sample ID**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Dec-10-2020 18:39:05<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BR511S | Initial Entry |

**5.b**

Header Text: C4591001

Visit: POT\_COVID\_CONVA 1 - Unscheduled Visit Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
on Dec/10/2020 Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Dec-10-2020 18:39:18<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID: BR511T</b> | Initial Entry |

**5.b Sample ID**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Dec-10-2020 18:39:18<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BR511T | Initial Entry |

**5.c**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Dec-10-2020 18:39:52<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID: BS2S4T</b> | Initial Entry |

**5.c Sample ID**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Dec-10-2020 18:39:52<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BS2S4T | Initial Entry |

**5.d**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Dec-10-2020 18:40:05<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sample ID: BS2S4V</b> | Initial Entry |

**5.d Sample ID**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Dec-10-2020 18:40:05<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BS2S4V | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1217

**Subject No:** 12171044

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Date   | Location        | User                          | Value        | Reason |
|--|-----------------|-------------------------------|--------------|--------|
| Dec-06-2020 17:18:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Created |        |

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1217

Subject No: 12171044

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Queries, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Category:**

| Date   | Location        | User                    | Value                               | Reason        |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Dec-06-2020 17:18:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ADVERSE EVENT | Initial Entry |

**2. AE ID:**

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Dec-06-2020 17:18:43<br>(UTC+03:00) Istanbul | 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   |
|--|-----------------|----------------------------|-------------------------------|--|
| Dec-08-2020 15:01:07<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)        | Query 1: Closed               | Response satisfies query                                     |
| Dec-07-2020 11:37:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | Query 1: Answered             | this sections have completed                                 |
| Dec-07-2020 10:20:16<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)           | Query 1: Opened               | DM: Please complete item # 4, 5, 8, 9, 10 and 13. Thank you. |
| Dec-06-2020 17:18:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Anxiety | Initial Entry  |

**4. Start Date Time:**

| Date   | Location        | User                       | Value                                     | Reason        |
|--|-----------------|----------------------------|---|---------------|
| Dec-07-2020 11:26:55<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Nov/21/2020 UNK:UNK | Initial Entry |

**5. Is the adverse event still ongoing?**

| Date   | Location        | User                | Value                           | Reason   |
|--|-----------------|---------------------|---------------------------------|--|
| Mar-13-2021 00:20:35<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 2:<br>Reissued<br>:Opened | FUP Date is reported as 04MAR2021, this should be the latest date reported for the subject. Either update stop date for AE or update |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)



Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1217

Subject No: 12171044

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Queries, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

|  |   |                            |  |  |
|--|---|----------------------------|--|--|
|  |   |                            |  | FUP date, or else explain. Thank You!  |
| Mar-12-2021<br>20:22:32<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)        | Query 2:<br>Answered   | data is correct.   |
| Mar-12-2021<br>18:23:38<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY<br>(b) (4)       | Query 2:<br>Opened   | DMW7692145;'End Date' is after 'Date of Completion/Discontinuation /Death' on the Disposition - Follow-up eCRF. Please clarify or correct. |
| Mar-12-2021<br>13:16:04<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br>NO<br>End Date Time :<br><br>Mar/10/2021 UNK:UNK | New Information  |
| Mar-12-2021<br>12:52:41<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | auto query<br>(autoquery)  | Query 1:<br>Closed   | Close Auto Query   |
| Mar-12-2021<br>12:52:41<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)        | <b>Data Entry:</b><br>NO<br>End Date Time :<br><br>Mar/10/2021 10:00   | New Information  |
| Mar-12-2021<br>12:16:43<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000                           | auto query<br>(autoquery)  | Query 1:<br>Opened   | 'Disposition Follow-up form is completed and this Adverse Event is still ongoing. Please review and update as appropriate.                 |
| Dec-07-2020<br>11:26:55                            | ACV0PFEINFP6000                           | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b>   | Initial Entry  |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Queries, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

|                         |  |  |     |  |
|-------------------------|--|--|-----|--|
| (UTC+03:00)<br>Istanbul |  |  | YES |  |
|-------------------------|--|--|-----|--|

6. Toxicity Grade:

| Date   | Location        | User                       | Value                   | Reason        |
|--|-----------------|----------------------------|-------------------------|---------------|
| Dec-06-2020 17:18:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <u>Data Entry:</u><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-06-2020 17:18:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <u>Data Entry:</u><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-07-2020 11:32:13<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <u>Data Entry:</u><br>NO | Initial Entry |

9. Is this event related to study treatment:

| Date   | Location        | User                       | Value             | Reason   |
|--|-----------------|----------------------------|-------------------|--|
| Dec-14-2020 19:54:08<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Juleen Gayed<br>(b) (4)    | Query 1: Closed   | Response satisfies query   |
| Dec-12-2020 23:27:18<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | Query 1: Answered | patient has a PCR results of the Covid-19 +. And after hospitalized due to Covid-19 treatment the anxiety has started related to general Covid 19 disease. |
| Dec-11-2020 19:10:38<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Juleen Gayed<br>(b) (4)    | Query 1: Opened   | Clin: Please clarify what is meant by the AE being related to  |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1217

Subject No: 12171044

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Queries, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

|  |                 |                            |  |  |
|--|-----------------|----------------------------|--|--|
|  |                 |                            |  | COVID-19, did the participant have a diagnosis of COVID-19 or were they anxious about the COVID-19 pandemic in general |
| Dec-07-2020 11:32:13<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>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>related to the covid-19 disease | Initial Entry  |

10. Latest Action Taken with Study Treatment:

| Date   | Location        | User                       | Value                                | Reason        |
|--|-----------------|----------------------------|--------------------------------------|---------------|
| Dec-07-2020 11:32:13<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

| Date   | Location        | User                       | Value                     | Reason        |
|--|-----------------|----------------------------|---------------------------|---------------|
| Dec-06-2020 17:18:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>YES | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date   | Location        | User                       | Value                    | Reason        |
|--|-----------------|----------------------------|--------------------------|---------------|
| Dec-06-2020 17:18:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur Yildirim<br>(b) (4) | <b>Data Entry:</b><br>NO | Initial Entry |

13. What was the outcome of this adverse event?:

| Date   | Location        | User                      | Value                                    | Reason           |
|--|-----------------|---------------------------|--|------------------|
| Mar-12-2021 12:53:03<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Closed                          | Close Auto Query |
| Mar-12-2021 12:53:03<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)          | <b>Data Entry:</b><br>RECOVERED/RESOLVED | New Information  |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1217

**Subject No:** 12171044

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Queries, Verified

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

|  |                 |                               |  |  |
|--|-----------------|-------------------------------|--|--|
| Mar-12-2021 12:52:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)     | Query 1: Opened                                      | For AE Anxiety:<br>Response to "What<br>was the outcome of<br>this adverse event?" is<br>'Not Recovered/Not<br>Resolved' but AE End<br>Date/Time is present. |
| Dec-07-2020 11:32:13<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>NOT RECOVERED/NOT RESOLV<br>ED | Initial Entry  |

**14. Did the adverse event cause the subject to be discontinued from the study?**

| Date   | Location        | User                          | Value                     | Reason              |
|--|-----------------|-------------------------------|---------------------------|---------------------|
| Dec-07-2020 11:33:54<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>NO  | Transcription Error |
| Dec-07-2020 11:30:42<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>YES | Transcription Error |
| Dec-06-2020 17:18:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>NO  | Initial Entry       |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Audit Trail

**Form Version:** 22-Apr-2020 21:03

**Form Status:**

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Date   | Location        | User                          | Value        | Reason |
|--|-----------------|-------------------------------|--------------|--------|
| Jan-11-2021 15:10:18<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Created |        |

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS -  
Audit Trail

**Form Version:** 22-Apr-2020 21:03

**Form Status:**

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

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| Date   | Location        | User                          | Value        | Reason |
|--|-----------------|-------------------------------|--------------|--------|
| Jan-11-2021 15:11:02<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | Form Created |        |

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. What is the medication identifier?**

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Jan-11-2021 15:10:18<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>1 | Initial Entry |

**2. Category:**

| Date   | Location        | User                    | Value                              | Reason        |
|--|-----------------|-------------------------|------------------------------------|---------------|
| Jan-11-2021 15:10:18<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>VACCINATIONS | Initial Entry |

**3. Concomitant Medications Pre-specified:**

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Jan-11-2021 15:10:18<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NO | Initial Entry |

**4. Medication:**

*Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).*

| Date   | Location        | User                          | Value                                   | Reason        |
|--|-----------------|-------------------------------|---|---------------|
| Jan-11-2021 15:10:18<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Influenza vaccine | Initial Entry |

**5. Date:**

| Date   | Location        | User                          | Value                             | Reason        |
|--|-----------------|-------------------------------|-----------------------------------|---------------|
| Jan-11-2021 15:21:36<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Dec/15/2020 | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. What is the medication identifier?**

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Jan-11-2021 15:11:02<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>2 | Initial Entry |

**2. Category:**

| Date   | Location        | User                    | Value                              | Reason        |
|--|-----------------|-------------------------|------------------------------------|---------------|
| Jan-11-2021 15:11:02<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>VACCINATIONS | Initial Entry |

**3. Concomitant Medications Pre-specified:**

| Date   | Location        | User                    | Value                    | Reason        |
|--|-----------------|-------------------------|--------------------------|---------------|
| Jan-11-2021 15:11:02<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NO | Initial Entry |

**4. Medication:**

*Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).*

| Date   | Location        | User                          | Value                                      | Reason        |
|--|-----------------|-------------------------------|--|---------------|
| Jan-11-2021 15:11:02<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>pneumococcal vaccine | Initial Entry |

**5. Date:**

| Date   | Location        | User                          | Value                             | Reason        |
|--|-----------------|-------------------------------|-----------------------------------|---------------|
| Jan-11-2021 15:21:19<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Dec/15/2020 | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)



**Header Text:** C4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Dec/03/2020

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

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*1. Date of Visit*

| Date   | Location        | User                          | Value                            | Reason        |
|--|-----------------|-------------------------------|----------------------------------|---------------|
| Dec-07-2020 11:38:30<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>Dec/3/2020 | Initial Entry |

**Header Text:** C4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Dec/03/2020

**Form:** UNPLANNED VISIT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

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*I. Assessments*

| Date   | Location        | User                          | Value                                 | Reason   |
|--|-----------------|-------------------------------|---------------------------------------|--|
| Dec-07-2020 11:43:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)     | Query 1: Deleted                      | Close Auto Query   |
| Dec-07-2020 11:38:48<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery)     | Query 1: Candidate                    | 'Contact Outcome is<br>ticked however<br>'CONTACT<br>OUTCOME' form is<br>not entered. Please<br>review and update as<br>appropriate. |
| Dec-07-2020 11:38:48<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>CONTACT OUTCOME | Initial Entry  |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned 1 - Unscheduled Visit on  
Dec/03/2020

**Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

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**1. Contact Type:**

| Date   | Location        | User                    | Value                                 | Reason        |
|--|-----------------|-------------------------|---------------------------------------|---------------|
| Dec-07-2020 11:43:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>TELEPHONE VISIT | Initial Entry |

**2. Was contact made?**

| Date   | Location        | User                          | Value  | Reason        |
|--|-----------------|-------------------------------|--|---------------|
| Dec-07-2020 11:43:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | Binnur<br>Yildirim<br>(b) (4) | <b>Data Entry:</b><br>YES<br>Date of Contact:<br><br>Dec/3/2020<br><br>Contact Outcome:<br><br>VISIT NOT REQUIRED, INVESTIGATOR DECISION | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Date of Completion/Discontinuation/Death :**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Nov-16-2020 17:00:35<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/10/2020 | Initial Entry |

**2. Phase of Disposition:**

| Date   | Location        | User                    | Value                             | Reason        |
|--|-----------------|-------------------------|-----------------------------------|---------------|
| Nov-16-2020 17:00:35<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>VACCINATION | Initial Entry |

**3. Status:**

| Date   | Location        | User                      | Value  | Reason  |
|--|-----------------|---------------------------|--|---|
| Nov-16-2020 17:01:46<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Closed  | Close Auto Query  |
| Nov-16-2020 17:00:35<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Opened  | Response to "Status" is NO LONGER MEETS ELIGIBILITY CRITERIA but "Specify Status" is missing. |
| Nov-16-2020 17:00:35<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>NO LONGER MEETS ELIGIBILITY CRITERIA | Initial Entry   |

**4. Specify Status:**

| Date   | Location        | User                | Value                                       | Reason        |
|--|-----------------|---------------------|---|---------------|
| Nov-16-2020 17:01:46<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Exclusion criterion 5 | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** Potential ReVax Initial Contact - Unscheduled **Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

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*1. Date of Visit*

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Jan-01-2021 20:20:59<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Dec/30/2020 | Initial Entry |

Header Text: C4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1217

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject No: 12171044

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:11

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**I. Select appropriate response - Is participant willing to return for Vaccination 3?**

| Date   | Location        | User                      | Value  | Reason  |
|--|-----------------|---------------------------|--|---|
| Mar-08-2021 17:30:48<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 2: Closed  | Response satisfies query  |
| Mar-06-2021 20:32:49<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 2: Answered  | Woc page was updated  |
| Mar-05-2021 18:28:06<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 2: Reissued:Opened   | DM: Please update WOC page within DISP per query response. Thank you.   |
| Mar-05-2021 11:04:07<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 2: Answered  | data was updated  |
| Mar-05-2021 11:04:07<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible | data was updated  |
| Mar-04-2021 18:14:29<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 2: Reissued:Opened   | Please update WOC visit.  |
| Mar-04-2021 13:12:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 2: Answered  | subject was withdraw consent  |
| Mar-04-2021 04:43:23<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 2: Opened  | DM: Participant is eligible and confirmed to have received Placebo on the Further Vaccination Confirmation CRF, However Date Written Consent Obtained is missing in Informed Consent - Further Vaccination CRF. Kindly review and update, else clarify. |
| Jan-05-2021 13:56:02<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>Participant is willing to return for Vaccination 3                               | Changed Information   |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** Potential ReVax Initial Contact - Unscheduled

**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:25

**Form Status:** Data Complete, Frozen

**Site No:** 1217

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject No:** 12171044

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:11

|  |                 |                           |  |   |
|--|-----------------|---------------------------|--|---|
|  |                 |                           | Participant is:<br><br>eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2  |   |
| Jan-04-2021 14:14:24<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Closed  | Close Auto Query  |
| Jan-04-2021 11:57:28<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4), (b) (6)          | Query 1: Opened  | The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date. |
| Jan-01-2021 20:21:08<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate   | The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date. |
| Jan-01-2021 20:21:08<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>Participant is willing to return for Vaccination 3<br>Participant is:<br><br>eligible and NOT confirmed to have received only placebo at Vaccination 1/2 | Initial Entry   |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

Header Text: C4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1217

Subject No: 12171044

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Date of Completion/Discontinuation/Death :**

| Date   | Location        | User                | Value                            | Reason        |
|--|-----------------|---------------------|----------------------------------|---------------|
| Mar-12-2021 12:16:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Mar/4/2021 | Initial Entry |

**2. Phase of Disposition:**

| Date   | Location        | User                    | Value                           | Reason        |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Mar-12-2021 12:16:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>FOLLOW-UP | Initial Entry |

**3. Status:**

| Date   | Location        | User                      | Value                                       | Reason   |
|--|-----------------|---------------------------|---|--|
| Mar-12-2021 12:23:03<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Closed                             | Close Auto Query   |
| Mar-12-2021 12:16:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Opened                             | Response to "Status" is WITHDRAWAL BY SUBJECT but "Specify Status" is missing. |
| Mar-12-2021 12:16:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>WITHDRAWAL BY SUBJECT | Initial Entry  |

**4. Specify Status:**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Mar-12-2021 12:23:03<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>He withdrew from the study because he give up vaccinated. | Initial Entry |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)



Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1217

Subject No: 12171044

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Date Treatment Unblinded :**

| Date   | Location        | User                | Value                             | Reason        |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Jan-04-2021 14:14:24<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Dec/30/2020 | Initial Entry |

**2. Primary Reason for Unblinding:**

| Date   | Location                                  | User                 | Value                     | Reason   |
|--|---|----------------------|---------------------------|--|
| Mar-10-2021 03:06:52<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000                           | (b) (4), (b) (6)     | Query 1: Closed           | Response satisfies query   |
| Mar-09-2021 12:51:55<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)  | Query 1: Answered         | The subject wanted to have the third vaccine. So the subject was eligible for the 3rd vaccination when unblinding was performed (30dec2020). However subject was not want to move on the study and gave up to the vaccination 3-4, withdraw consent from the study |
| Mar-08-2021 18:14:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)  | Query 1: Reissued: Opened | Please note that if reason for Unblinding is ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION then "Participant is willing to return for Vaccination 3" should be selected on the FURTHER VACCINATION CONFIRMATION form. Please review and update accordingly         |
| Mar-06-2021 20:35:22<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000                           | (b) (4),<br>(b) (6)  | Query 1: Answered         | Woc page was updated. Because the subject gave up vaccination.   |
| Mar-06-2021 07:09:44<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY<br>(b) (4) | Query 1: Opened           | DMW7624468; Primary Reason for Unblinding is "ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION", but "Participant is willing to return  |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1217

**Subject No:** 12171044

**Generated By:** (b) (4)

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

|  |                 |                     |   |  |
|--|-----------------|---------------------|---|--|
|  |                 |                     |   | for Vaccination 3" is not selected in the Further Vaccination Confirmation CRF. Please review and update as appropriate. |
| Jan-04-2021<br>14:14:24<br>(UTC+03:00)<br>Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry</b><br>:<br>ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION | Initial Entry  |

Header Text: C4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1217

Subject No: 12171044

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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**I. Withdrawal of Consent Date :**

| Date   | Location        | User                | Value                                | Reason   |
|--|-----------------|---------------------|--------------------------------------|--|
| Mar-12-2021 19:28:15<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Closed                      | Response satisfies query   |
| Mar-12-2021 12:23:45<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Answered                    | data was updated   |
| Mar-12-2021 04:53:00<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Opened                      | CLINQUERY:<br>Withdrawal of Consent to the study is reported, but subject is not reported as off study (FUP page not entered). Please review if entry is correct and, if so, please add data to FUP tab to reflect end of study. |
| Mar-06-2021 20:30:41<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Mar/4/2021     | New Information  |
| Mar-06-2021 20:29:47<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Mar/3/2021     | Initial Entry  |
| Mar-06-2021 20:29:09<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b>                   | Initial Entry  |
| Jan-04-2021 14:20:05<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry  |

090177e196ae2f28\Final\Final On: 01-Apr-2021 03:36 (GMT)

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1217

**Subject No:** 12171044

**Generated By:** (b) (4)

**Form:** DEATH DETAILS CODED - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1217) Kocaeli University Faculty of Medicine

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:11

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***1. Date of Collection / Notification of Death:***

| <b>Date</b>                                  | <b>Location</b> | <b>User</b>         | <b>Value</b>                         | <b>Reason</b> |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Jan-04-2021 14:20:22<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

Header Text: C4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1217

Subject No: 12171044

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1217) Kocaeli University Faculty of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:11

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**1. Subject Status**

| Date   | Location        | User                    | Value                                     | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Mar-12-2021 12:16:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DISCONTINUED        | Initial Entry |
| Nov-16-2020 17:00:35<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DISCONTINUED        | Initial Entry |
| Nov-04-2020 15:44:01<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ENROLLED/RANDOMIZED | Initial Entry |
| Nov-04-2020 14:03:22<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SCREENED            | Initial Entry |

**2. Subject Status Date**

| Date   | Location        | User                    | Value                             | Reason        |
|--|-----------------|-------------------------|-----------------------------------|---------------|
| Mar-12-2021 12:16:43<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Mar/4/2021  | Initial Entry |
| Nov-16-2020 17:00:35<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Nov/10/2020 | Initial Entry |
| Nov-04-2020 15:44:01<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Nov/4/2020  | Initial Entry |
| Nov-04-2020 14:03:22<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Nov/4/2020  | Initial Entry |

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**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1217

**Subject No:** 12171044

**Generated By:** (b) (4)

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| Nov-18-2020 09:14:09<br>(UTC+03:00) Istanbul | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Click Here to Enable | Initial Entry |