# Standard Operating Procedure Study name blood sampling, labeling, storage and shipment.

Study name: Full name of study/biobank (e.g. Prospective Breast Cancer Biobank)

Study acronym: Short study name formed from the initial components of the full study name (e.g. PBCB)

Protocol ID no. XxXxX  
EudraCT no. 2021-123456  
Coordinating investigator: Navn Navnesen  
Sponsor: Akershus University Hospital

## Contact information, Site 1: Akershus University Hospital

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| --- | --- | --- | --- |
| **Name** | **Title** | **email** | **Mobile Phone** |
| Navn Navnesen | Coordinating investigator |  |  |
|  | Deputy coordinating investigator/Medical officer |  |  |
|  | Principal Investigator |  |  |
|  | Administrative coordinator |  |  |
|  | Study nurse |  |  |
|  | Study nurse |  |  |
|  | System administrator eBiobank |  |  |
|  | Sub-investigator |  |  |
|  | Research advisor biobanking |  |  |

## Contact information, Site 2:

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| --- | --- | --- | --- |
| **Name** | **Title** | **email** | **Mobile Phone** |
|  | Principal Investigator |  |  |
|  | Study project coordinator Blood samples |  |  |
|  | Research advisor biobanking |  |  |

## Contact information, Site 3:

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Title** | **email** | **Mobile Phone** |
|  | Principal Investigator |  |  |
|  | Research advisor biobanking |  |  |
|  | Study nurse |  |  |

## Flow-chart blood sampling

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Trial period** | | |
|  | **Week 0** | **Week 9-12** | **Week 72-76** |
| **Sample type** | **Baseline/Visit 1** | **Visit 2** | **Visit 3** |
| Buffy coat | X |  |  |
| Serum | X | X | X |
| EDTA-plasma | X | X | X |
| Heparin-plasma | X | X | X |

Blodprøver tas ved baseline 1-2 uker postoperativt. Pasient fyller samtidig ut samtykkeskjema. Blodprøver tas deretter ved visitt 2 og 3 henholdsvis 3 og 18 mnd etter baseline blodprøver.

## 

## Sample procedure

|  |  |
| --- | --- |
| **Sample tubes and order of draw** | |
| 1. 2 x serum-gel 5ml 2. 1 x Heparin-plasma 4ml 3. 3 x EDTA-K2 4 ml: plasma (all visits) + buffy coat (visit 1)   Total blood volume per patient: 26 ml  20 cryotubes 0.5 ml.  Use colored caps on the aliquots: RED cap = serum GREEN cap = Heparin-plasma LILAC cap = EDTA-plasma White cap = buffy coat | Image result for serum gel tube Image result for serum gel tube Image result for heparin tube 4ml, greiner Image result for EDTA K2 4ml, greiner Image result for EDTA K2 4ml, greinerImage result for EDTA K2 4ml, greiner  2x Serum-gel 5ml 1 x Heparin 4ml 3 x EDTA-K2 4ml  Invert the tubes 10 times after blood sampling. (one inversion is equal to a complete turn of the wrist, 180° back and forth). After mixing, the blood tubes should be put in an upright vertical position in room temperature (RT, 18-20 ⁰C).   1. **Serum-gel tubes:** Allow the blood to clot while standing in an upright vertical position at room temperature (RT, 18-20 ⁰C) for 30-60 min. Centrifuge at 2200 G for 10 min at RT. Transfer the serum supernatant from both serum tubes to a 15 ml tube using a transfer pipette. Pipette up and down to mix (homogenize) the serum before aliquotation. Transfer the homogenized serum into 0.5 ml Sarstedt micro tubes (6 aliquotes á 0.5 ml). Seal with red screw caps. 2. **Heparin-plasma tubes:** Centrifuge at 2200 G for 10 min at RT. Transfer the plasma supernatant to a 15 ml tube using a transfer pipette. Pipette up and down to mix (homogenize) the heparin-plasma before aliquotation. Transfer the homogenized heparin-plasma into 0.5 ml Sarstedt micro tubes (3 aliquotes á 0.5 ml). Seal with green screw caps. 3. **EDTA-K2 tubes:** Centrifuge at 2200 G for 10 min at RT. This separates the blood into 3 distinct phases the upper layer is the plasma, the middle narrow layer is the buffy coat/white blood cells and the lower layer is the red blood cells. **EDTA-plasma** (all visits): Transfer the plasma supernatant to a 15 ml tube using a transfer pipette. Pipette up and down to mix (homogenize) the EDTA-plasma before aliquotation. Transfer the homogenized EDTA-plasma into 0.5 ml Sarstedt micro tubes (9 aliquotes á 0.5 ml). Seal with purple screw caps.   **Buffy coat/white blood cells** (only at visit 1)**:** Using a transfer pipette, carefully transfer the narrow middle layer into 0.5 ml Sarstedt micro tubes (2 aliquotes á 0.5 ml). Seal with white screw caps.  Freeze the aliquotes immediately at - 80⁰C for longtime storage.   Donor-id, barcode/sample-id, collection date, collection time, visit number, sample type, additive and time to store must be recorded in Sample Log Form (eBiobank).  Hemolysis or deviations from the procedure should be recorded in Sample Log Form (eBiobank) under Flag comment. |

## Flow chart processing of blood

# Image result for serum gel tube Image result for heparin tube 4ml, greiner Image result for EDTA K2 4ml, greiner

EDTA-plasma and ‘buffy coat’

Heparin-plasma

Serum-gel

RED cap = serum  
GREEN cap = Heparin-plasma  
LILAC cap = EDTA-plasma  
White cap = buffy coat

Record sample information in Sample Log Form (eBiobank).

Freeze the samples immediately at - 80⁰C for longtime storage.

Transfer the serum, plasma layers or ‘buffy coat’ into labeled cryotubes using a pipette.  
 The material should be apportioned into 0.5 ml aliquots.

   

‘Buffy coat’ NB! Visit 1 only

EDTA-plasma

Serum

Heparin-plasma

Allow blood to clot at RT 30-60 min.

Centrifuge in a swing-out centrifuge at 2200 G for 10 min at RT.

## Labeling of cryotubes

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Serum** | **EDTA-plasma** | **Heparin-plasma** | **Buffy coat** |
| eBiobank compatible labels will be made by Navn Navnesen and the eBiobank system administrator.  **NB! Write date with a water, - and cryo-proof pen.** | Study name-01 V1, 01-001 Serum 0.5ml Dato:  01 = Site number  V1 = visit number  01-001 = donor-id/patient id QR-code: P1-10001 | Study name-01 V1, 01-001 EDTA-plasma 0.5ml Dato: | Study name-01 V1, 01-001 Heparin-plasma 0.5ml Dato: | Study name-01 V1, 01-001 Buffy coat 0.5ml Dato: |
| Study name-01 V2, 01-001 Serum 0.5ml Dato: | Study name-01 V2, 01-001 EDTA-plasma 0.5ml Dato: | Study name-01 V2, 01-001 Heparin-plasma 0.5ml Dato: |  |
| Study name-01 V3, 01-001 Serum 0.5ml Dato: | Study name-01 V3, 01-001 EDTA-plasma 0.5ml Dato: | Study name-01 V3, 01-001 Heparin-plasma 0.5ml Dato: |  |

More examples of eBiobank compatible labels can be found [here](https://forskerstotte.no/filer/biobanker/docs/Labels%20i%20eBiobank.pdf).

## Labeling of boxes and sample positioning

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| Label each box with the following information:  Biobank, Site no, Box no.  Example first box, site 1: Study name**, Site 01, Box 01**  Sample positioning:  Box 9x9 Start at position A1 and fill the boxes  row by row from left to right.  Mark position A1. | Study name**, Site 01, Box 01**  **Cryobox 9x9**   |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | | A1 | A2 | A3 | A4 | A5 | A6 | A7 | A8 | A9 | | B1 | B2 | osv |  |  |  |  |  |  | | C1 | C2 | osv |  |  |  |  |  |  | | D1 | D2 | osv |  |  |  |  |  |  | | E1 | E2 | osv |  |  |  |  |  |  | | F1 | F2 | osv |  |  |  |  |  |  | | G1 | G2 | osv |  |  |  |  |  |  | | H1 | H2 | osv |  |  |  |  |  |  | | I1 | I2 | osv |  |  |  |  |  |  | |

## eBiobank

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| --- | --- |
| The digital tracking system eBiobank will be used in the study. | Samples information is registered directly into eBiobank (Site 1) or into the eBiobank Sample Log Form (Site 2-3). |

## Storage of boxes with cryotubes from Ahus

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Freeze the samples at -80⁰C. Location: Ahus Room:  Freezer: | **Site 01- Akershus University Hospital**   |  |  | | --- | --- | | **Freezer:** | | | **Rack** | **Shelf** | |  |  | |  |  | |  |  | |  |  | |

## Shipment of samples to Ahus from Site 2 and 3

|  |  |
| --- | --- |
| Procedure | Boxes with cryotubes should be shipped on dry-ice to Akershus University Hospital upon agreement with study nurse Navn Navnesen and/or coordinator Navn Navnesen. The samples should be shipped in full boxes, 8 boxes (9x9) at a time, using TNT as courier. Akershus University Hospital will order shipment by TNT after being contacted by the other sites (50Wx50Hx50D shipmentbox with dry ice). Each site should fill out one Sample Log Form (eBiobank) for each box. These files should be sent by email to Navn Navnesen  (navn.navnesen@ahus.no) in connection with the shipment. The Sample Log Form will be imported to eBiobank upon arrival, and the samples will be stored in allocated freezers at Ahus. |
| Shipment address | Til Akershus Universitetssykehus  Navn Navnesen    Sykehusveien 25 1478 Lørenskog  Tlf: |

## Storage of boxes with cryotubes from site 2 and 3

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Freeze the samples at -80⁰C . Location: Ahus  Room:  Freezer: | **Site 02**   |  |  | | --- | --- | | **Freezer:** | | | **Rack** | **Shelf** | |  |  | |  |  | |  |  | |  |  | |
| Freeze the samples at -80⁰C . Location: Ahus  Room:  Freezer: | **Site 03**   |  |  | | --- | --- | | **Freezer:** | | | **Rack** | **Shelf** | |  |  | |  |  | |  |  | |

## Site information

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| --- | --- |
| **Site** | **Site number** |
| Akershus University Hospital | 1 |
|  | 2 |
|  | 3 |

## Product ordering information

|  |  |  |
| --- | --- | --- |
| **Product** | **Vendor** | **Order no** |
| Micro tube 0.5ml, PP | sarstedt | 72.730.003 |
| Screw cap (76.716.xxx different colours) | sarstedt | 76.716.721(red), .726(green), .755(lilac), .757(white) |
| CRYOBOX 50MM WHITE W. DIVIDERS 9X9 | VWR | 479-1438 |
| Greiner Bio-One VACUETTE® TUBE 4 ml K2EDTA | Med-kjemi | G454209 |
| Greiner Bio-One VACUETTE® Serum Gel 5 ml | Med-kjemi | G456073 |
| VACUETTE® Li-Heparin Gel 4 ml | Med-kjemi | **G454008** |
|  |  |  |

## Estimated budget

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Totalt behov** | **Pris per år** |  | **Total pris X år** |
| Leie av fryseplass | X liter |  |  |  |
| eBiobank lisens | 1 lisens |  |  |  |
| Utstyr (blodprøveglass, cryorør, lagringsbokser etc). |  |  |  |  |
|  | **Antall** | **Pris per time** | **Antall timer totalt** | **Total pris** |
| Lage merkelapper og sende til sites | X etiketter | X NOK/time |  |  |
| Prøvemottak og registrering i eBiobank | X alikvoter/X bokser | X NOK/time |  |  |
| **Registrering av prøver ved Ahus** | X alikvoter/X bokser | X NOK/time |  |  |
| **Utplukk av prøver fra eBiobank** |  | X NOK/time |  |  |
|  |  |  |  |  |
|  | **Antall bokser** | **Pris per Medpack17** | **Totalt antall Medpack17** |  |
| **Forsendelse av prøver på tørris, f.eks. Courier TNT, MedPack 17, innad i Norge** | X bokser |  |  |  |
|  |  |  |  |  |
| **Totale utgifter for BIOBANK** |  |  |  | **NOK** |