

Blood sample handling and storage

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Anmerkung

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1. Introduction

This process describes the handling, storage and transport of blood samples for the EMINENT-ICH RCT. Neurofilament light chain (NfL), Glial fibrillary acidic protein (GFAP), Calcium binding protein S100B (S100B) and Interleukins 1-12 are not routinely analysed and therefore, handling and storage has to be controlled. This process describes step-by-step the required materials, procedures, and contacts required for adequate handling, transport and storage of the blood samples. A separate work instruction describes the process of aliquotation in detail.

2. Scope

All blood samples assessed for the EMINENT-ICH RCT.

3. Terms and abbreviations

- NfL: Neurofilament light chain
- GFAP: Glial fibrillary acidic protein
- S100B: Calcium binding protein S100B
- IL: Interleukin
- rpm: rounds per minute

4. Roles and Responsibilities

Study Nurse/Nurse

- Take blood samples
- send blood samples to laboratory
- take note on time blood sample was drawn

Investigator

- Take blood samples
- send blood samples
- take note on time blood sample was drawn
- order blood samples to be taken

Laboratory personnel

- Processing of samples to aliquots
- label samples
- freeze samples at -80°C
- take note of time samples were frozen

Sponsor/PI

- collaboration with local laboratories at DBM

5. Process

5.1. Material needed

Materials needed for acquiring blood samples are:

- 2x native serum test tubes (yellow cap)
- puncture set
- disinfection
- sterile wipes
- tournique
- order sheet for patient indicating patient ID and visit for blood sampling ([EMINENT-ICH_order sheet_V1.0_260623.pdf¹](#))

All materials are to be prepared before blood samples are taken.

5.2. Acquiring blood samples

The investigator or study nurse/nurse will ask the patient to provide a blood sample with a venous puncture. Alternatively, an already installed drip-port can be used to avoid puncture or during ICU stay or an arterial blood sample can be acquired over the indwelling arterial catheter. Arterial blood samples have to be indicated on the patient ID form.

Blood is taken and the patient ID-form is filled out by the investigator/study nurse/nurse with the following details:

- Patient study ID (USB-NNN)
- Study visit
- Date of blood sampling (DD/MM/YY)
- Time of blood sampling (hh:mm)

1. <https://orca.dkfbasel.ch/download/process/24d336a6-893e-11ee-b913-0242ac120005>

5.3. Send blood samples

Patient blood samples are sent **together** with the order sheet to the laboratory for processing as soon as possible. The laboratory personnel is to be informed about the imminent arrival of blood samples.

Blood samples are to be packed and sent according to the regulation for delivery of blood samples.

Laboratory site contacts are:

- Basel: USB Labor Studienkoordination (phone 061 32 85396)

5.4. Process blood samples

Laboratory personnel accepts the incoming blood samples and proceeds with the aliquotation process as detailed in the working instruction ([Work Instructions Laboratory: Blood sample processing](#)¹). Laboratory personnel is required to process the sample **within 2 hours after the blood sample was taken**. After processing, laboratory personnel will be required to label the aliquots as follows:

- Patient study ID (USB-NNN)
- Study Visit
- Target laboratory (either GUZ [Guzman Labor] or KUJ [Kuhle Labor])

The aliquots are then frozen in a -80°C freezer and laboratory personnel is required to indicate the time of freezing on the order sheet. The -80°C freezer must be under 24h surveillance with built-in alarm systems. The laboratory site contacts are responsible to organize maintenance and repair if necessary.

1. <https://orca.dkfbasel.ch/processes/9d3301f6-b9de-11ed-abbf-1bc4667e534c/current>

6. Process Diagram

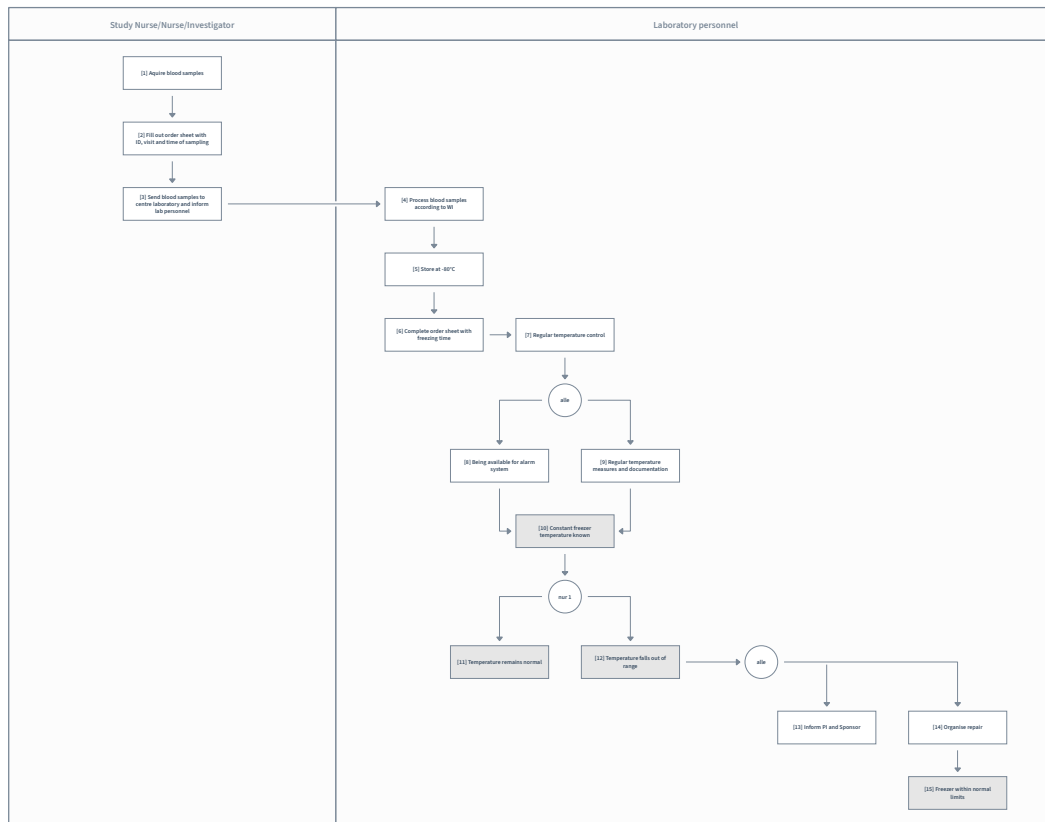


Diagramm 1

7. Metrics

- Time from sampling to freezing

8. Document filing

The sample storage log will be filed in the ISF and in the central laboratory.

9. References

- [Work Instructions Laboratory: Blood sample processing](#)¹
- [EMINENT-ICH_order sheet_V1.0_260623.pdf](#)²

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- [EMINENT-ICH_WI_short_form_blood_sample_processing_V1.0.pdf](#)¹

1. <https://orca.dkfbasel.ch/processes/9d3301f6-b9de-11ed-abbf-1bc4667e534c/current>

2. <https://orca.dkfbasel.ch/download/process/169cf9c7-893f-11ee-b913-0242ac120005>

1. <https://orca.dkfbasel.ch/download/process/28333ad6-893f-11ee-b913-0242ac120005>

10. Details zu Diagramm 1

[1] Acquire blood samples

[2] Fill out order sheet with ID, visit and time of sampling

[3] Send blood samples to centre laboratory and inform lab personnel

[4] Process blood samples according to WI

[5] Store at -80°C

[6] Complete order sheet with freezing time

[7] Regular temperature control

[8] Being available for alarm system

[9] Regular temperature measures and documentation

[10] Constant freezer temperature known

[11] Temperature remains normal

[12] Temperature falls out of range

[13] Inform PI and Sponsor

[14] Organise repair

[15] Freezer within normal limits

Änderungsverzeichnis

Version	Beschreibung
Version: 1.0.0 (aktuell)	03.03.2023: Initial version of SOP