Proficiency test to evaluate the processing and shipment of blood samples in biobanks

- Registration -

Proficiency test provider (research context)

Jena University Hospital
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Coordination and contact

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Participant-ID (filled by UKJ)

Participant

Please fill in your institution’s name and address just as you'd like them to appear on your certificate.

The identity of the participants, as well as the results of the proficiency test, is treated confidentially and is only accessible to individuals involved in implementing the program.

Registration Proficiency test modules – Overview

The following modules are mandatory components of the proficiency test and are included in the test scheme.

Module 1: Testing the homogeneity of plasma aliquots after centrifugation of blood samples by measuring the platelet count.

Module 2: Testing the volume precision and accuracy of plasma aliquots after centrifugation of blood samples and plasma aliquoting by gravimetric determination of the volume. As part of the test scheme, aliquots of 200 µL and 400 µL are prepared.

Please select the scheme with which you would like to participate in the proficiency test!

Participation: ◯ Manually* ◯ Automatic** ◯ Both***

*Manual - Aliquoting is performed manually using a piston-operated pipette.;
**Automatic - Aliquoting is performed using an automated pipetting system (e.g., pipetting robot);
***Both - You intend to perform aliquoting both manually and automatically.

As part of your service catalog, do you provide precise volume specifications that allow for immediate downstream processing of aliquots, such as in automated ELISA workflows?

◯ Yes ◯ No

Module 3: Verification of entry control and corresponding documentation of the participating facility.

Module 4: Assessment of the shipping and packing of potential infectious samples according to ADR/IATA (UN3373) packing instruction P650/PI650

Module 5: Temperature monitoring of samples during shipment on dry ice

Module 6: Identification of contamination using NMR

Optional:

Module 7 (optional): Verification of the sample report in compliance with ISO 20387 and DIN/TS 13283.
This optional module involves the evaluation of the sample report according to the requirements set out in ISO 20387. The biobank must submit a report during the proficiency test that meets at least the specifications outlined in section 7.12.2, with particular focus on the content of the sample report.

Participation: ◯ Yes ◯ No

Registration formalities

We kindly ask all participants to provide the required information in full and, if not already done, to designate a contact person for communication and coordination of the EQA scheme. This contact person will receive all relevant process information, forms, evaluations, and the final certificate for the EQA scheme.

Contact information

Contact person at the participating facility (if more than one contact person, please specify all): Name, Surname; E-mail, Telephone

Delivery address of the participating facility: **Institute**; **Address**; Address additions (if applicable); **Consignee (+Telephone)**

Billing information

Institute; **Address**; additional address details (if applicable); **recipient (including phone number)**; and any other information required for invoicing, especially reference numbers, process numbers or similar.

VAT (Value Added Tax) number (required for participation):

More details

In this section, please enter information on your automatic pipetting systems and/or, in the case of manual pipetting, on your pipettes used for the proficiency test.

	Manufacturer/Type	Performance data
Example	e.g.: Hamilton / Microlab Star M	Accuracy - Precision (V_k) -
Please fill in		

	For manual pipetting	
	Manufacturer /Type / Nominal volume*	**DIN ISO 8655:2****
Example Pipette 1	e.g.: Eppendorf / EP Research® plus G, Basic, Single-channel pipette, **variable, 100 - 1000 µl**, blue	Calibrated / metrologically traceable / no
Please fill in		
Please fill in		

* For the nominal volume of the pipette, please specify whether it is a fixed-volume pipette (fixed) or a variable-volume pipette (variable)

** Please state whether you calibrate the pipettes according to DIN ISO 8655:2 (calibrated) or whether your pipettes are metrologically traceable (metrologically traceable) - if neither of these applies, please state "no".

Cryotubes

Please enter here the type of cryotubes you will use and send to us for the proficiency test.

	Manufacturer /Type / volume	Ordering number
Example Cryotube 1	e.g.: Azenta / Fluid X 0,7 mL 2D Barcoded Storage Tubes	68-0702-11N
Please fill in		
Please fill in		

Blood collection tubes

Please enter here the type of blood collection tubes (only EDTA and Citrate) that can be processed (e.g.: for pipetting robot according to participant's SOPs)

	Manufacturer /Type / volume	Volume & Ordering number
Example Blood collection tube	e.g.: S-Monovette EDTA K3E; 4.9 mL, 7.5 mL, 9 mL	4.9 mL – 04.1931.010 7.5 mL - 01.1605 9 mL – 02.1066.001
Please fill in		
Please fill in		

Surface disinfectant / rinsing solution

Please specify the type of surface disinfectant you use during your laboratory activities (e.g., for cleaning work surfaces or pipetting robots), and, if applicable, the type of rinse solution used in your pipetting robot.

	Manufacturer /Type	Ordering number
Example Surface disinfectant	e.g.: Braun, Meliseptol	19761
Please fill in		

Standard pipetting scheme

Shown is the standard scheme for the proficiency test. **The number, size and type of blood collection tubes** supplied depends on the individual participant and will be adjusted individually after registration according to the specifications of the respective participants.

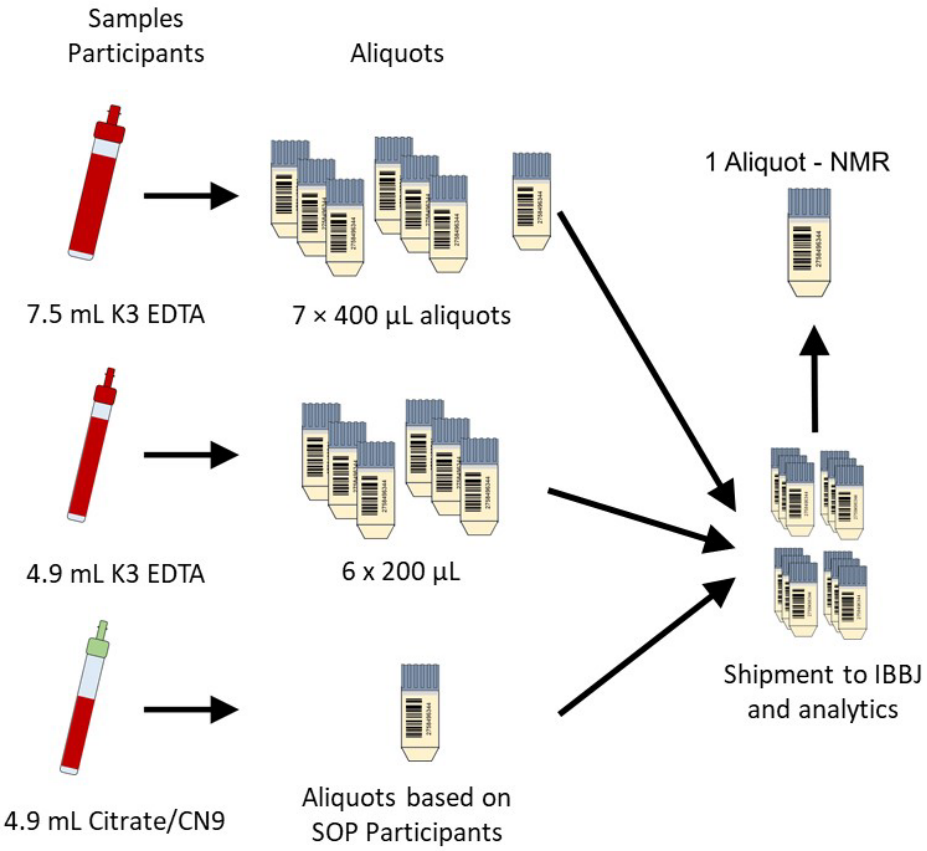

Figure 1 - Scheme for manual aliquoting of samples at participating sites.

Blood collection tubes can be Sarstedt-Monovette, BD-Vacutainer or Greiner-Vacuette

To ensure comparability between participating institutions, the aliquoting scheme (Figure 1) is mandatory for manual pipetting using a piston-stroke pipette. The 4.3 mL citrate/9NC monovette/vacuette/Vacutainer should be aliquoted according to the SOP of the participating institution without further specification to the aliquot volume.

General Information

1. Sample material

The samples provided by the IBBJ testing laboratory consist of whole blood from a voluntary donor, transferred from a blood bag into citrate/CN9 and K3-EDTA blood collection tubes (Sarstedt, BD, Greiner).
The samples are to be handled like diagnostic samples / patient samples. All safety instructions provided in the accompanying documentation, as well as all applicable legal regulations and professional standards of care for handling biological and potentially infectious materials, must be strictly followed. The samples are intended exclusively for proficiency testing purposes and must not be misused in any way. Proper disposal of the samples is mandatory after completion of the testing.

2. Shipping

The samples will be shipped by the IBBJ testing laboratory via a transport company determined by the IBBJ testing laboratory on the dates specified during the proficiency test. After the samples have been handed over to the transport company, the risk of loss or damage is transferred to the participant.

2.1. Samples do not reach the participant / are delayed

a) The participant must notify the IBBJ testing laboratory immediately if the samples are not received within the expected arrival time following the dispatch date. In the event of delayed sample delivery, the participant is required to coordinate with the IBBJ testing laboratory regarding the continuation of the proficiency test.

b) If the samples do not arrive, the IBBJ testing laboratory will contact the shipping service provider and initiate a shipment investigation. If the samples cannot be located and the participant is not at fault, the shipping service provider will be held responsible. In such cases, the participant will not incur any costs but will no longer be able to participate in the EQA scheme.

c) The participant is responsible for keeping their information—particularly delivery, billing, and certificate addresses—up to date at all times. Any costs resulting from outdated or incorrect data shall be borne by the participant. This also applies to costs incurred for return shipment or disposal of samples due to refusal of acceptance.

2.2. Samples do not reach the participant intact / temperature specifications were not met

The participant must immediately inform the IBBJ testing laboratory if the samples are received in a damaged condition or if the prescribed temperature conditions were not maintained at the time of receipt. After consultation, the IBBJ testing laboratory will decide together with the participant whether it is advisable to continue or discontinue the proficiency test. The final decision will be made on a case-by-case basis.

2.3. The samples do not arrive / do not arrive in time at the IBBJ testing laboratory

Participants are responsible for arranging shipment with a suitable shipping service provider. Each participant must ensure that the samples arrive at the IBBJ testing laboratory as announced, within the EQA scheme period, and during regular working hours (Monday to Friday, 7:00 a.m. to 3:00 p.m.). Any costs arising from delayed delivery or loss of the samples are to be borne by the participants.

3. Evaluation and results

Each participant receives a detailed report for the individual modules, as well as an overall assessment in the form of an **igLoo score**. The igLoo score uses a color-coded, six-level scale from **A to F** to indicate the performance of the biobank in the respective processes.

In addition, each participant is offered a **feedback session** (45–90 minutes) to review the results. During this session, the evaluation criteria are explained in detail, and any deviations from expected outcomes are discussed.

Date: .....

Signature