

Revision changes

06-06-2023: Centrifuge brake is changed in this SOP.

11-09-2023: G-force first centrifuge step changed.

1. Goal

To describe how plasma for cell-free DNA must be prepared and stored for Radboud Biobank (RB) purposes, so that:

1. Interested parties including potential users know how the biomaterial has been handled.
2. The laboratory can assess whether they can process the biomaterial as described under paragraph 2 "Preparation".
3. The laboratory knows the requirements for the collection, processing and storage of the biomaterial to enable registration of deviations.
4. The collectors know the requirements for collection and transport of the biomaterial to ensure correct delivery.
5. The RB is able to attach this procedure to the biomaterial in storage to determine the fitness for purpose.

1.1 Scope of application

This procedure is applicable to all employees concerned at the RB, the collectors and the Radboud Laboratory for Diagnostics (RLD).

2. Protocol plasma for cell-free DNA

Collection

Delivery In three collection tubes.
Do **not** send the tubes to the laboratory with the pneumatic tube system but use internal transport.

Type of tube CE-IVD Cell-Free DNA collection tube, Roche Diagnostics 7832389001 or equivalent.

Temperature Keep tubes at room temperature until prepared for storage.

Preparation

Time until freezing Prepare and freeze the collected blood within 7 days of collection.

Centrifuge g-force: 1600g.
Time: 10 minutes.
Temperature: room temperature.
Brake: brake position 2

Processing Transfer the supernatant of each tube to a 5 ml polypropylene centrifugation tube (Eppendorf No. 0030119.401 or equivalent).

Centrifuge 5 ml polypropylene centrifugation tubes.

Processing g-force: 16.000g.
Time: 10 minutes.
Temperature: cooled at 4 °C.
Brake: brake position 5

Aliquotation of Supernatant.

Storage

Register Register the 5ml tubes in the Biobank Information Management System (BIMS) and attach a cryovial label.

Aliquotation	Transfer the supernatant of each centrifugation tube to a 5 ml polypropylene storage tube.
Type of tube	5 ml polypropylene tube with external thread and screw cap. (Fisherbrand No. 10-500-27 or equivalent).
Temperature	-80°C.

Miscellaneous

Deviations	Note all deviations from this procedure in the BIMS. Assess the samples macroscopically for the following deviations (haemolytic, icteric and lipemic) and register them in the BIMS.
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3. Quality assurance

Review takes place via i) an internal audit (available on request at radboudbiobank@radboudumc.nl) and ii) 2-monthly performance reviews of deviations registered in the BIMS (available on request at radboudbiobank@radboudumc.nl).

3.1 Performance indicator

95% of the collected samples have been prepared and stored within the parameters of this procedure.

4. Accountability

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4.1 Limitations

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5. Comments

It is the responsibility of the collectors to document in the clinical data if the blood is collected under fasting or non-fasting conditions.

6. Relevant documents

Qdocs, literature, legislation and codes of conduct, website etc.

link	Title
Qdoc 045014	Radboud Biobank voorschrift RLD (NB alleen bestemd voor medewerkers RLD)
Qdoc 078088	Monstermanagement RLD t.b.v. Radboud Biobank
Qdoc 084860	DVO RLD
Qdoc 015297	Bloedafname RLD: veneus en capillair