Revision changes

1. Goal

To describe how citrate plasma (2,7 ml) 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 is informed about the collection, processing and storage requirements to enable registration of deviations.
- 4. The collectors are informed about the requirements for the 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 Citrate plasma 2,7 ml

Collection Fasting patient	Dependent on the requirements of the individual collection/project.
Delivery	In collection tube.
Type of tube	Standard 2,7 ml tube with anticoagulant (3,2% buffered sodiumcitrate). 13x75mm, PET/PP with Hemogard Safety Closure. BD 363048 or equivalent.
Temperature	Keep tubes at room temperature until prepared for storage.
Preparation Time until freezing	Prepare and freeze the collected blood as soon as possible. Aim: within 2 hours. Maximum: within 4 hours.
Centrifuge	g-force:2000 g.Time:10 minutes.Temperature:room temperature
<u>Storage</u> Register	Register the microtubes in the Biobank Information Management System (BIMS, <u>Qdoc 079734</u>) and attach a cryovial label.
Aliquotation	Store the supernatant in 2 aliquots of 0,5 ml. If there is biomaterial left over add it to the 2 aliquots.
Type of tube	2 ml polypropylene microtube and screw-top with O-ring. GREI722301UMC and GREI368380UMC 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.

3. Quality assurance

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

3.1 Performance indicator

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

4. Accountability

4.1 Limitations

- Hemolytic, icteric and lipemic samples can influence the analysis and deviations should be documented.
- For some assays like the Lupus Anticoagulant assay the plasma must be "platelet-free" and specific centrifugation protocols are published and recommended.
- Some coagulation assays (eg. the aPTT in heparin monitoring) are more sensitive to preanalytical variations than others (eg. the PT/PT-INR).

5. Comments

For specific diagnostic tests validated in the Radboudumc under ISO15189 check the recommendations for the collection tube, pre analysis and stability in the <u>eLabgids</u>.

6. Relevant documents

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

link	Titel
Qdoc 084860	DVO RLD – Radboud Biobank
Qdoc 078088	Monstermanagement RLD t.b.v. Radboud Biobank
Qdoc 045014	Radboud Biobank voorschrift RLD
Qdoc 015297	Bloedafname RLD: veneus en capillair
Qdoc 079734	Handleiding Itemtracker
Link	eLabgids