Revision changes

1. Goal

To describe how a serum Serum Separation Tube (SST) tube (8,5 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 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 Serum SST (8,5 ml)

Collection	
Fasting patient	Dependent on the requirements of the individual collection/project.
Delivery	In collection tube.
Type of tube	Standard SST serum tube, with gel and clot activator. BD tube 367953 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.
Coagulation time	Minimum 30 minutes, maximum 60 minutes. Coagulation takes place at room temperature.
Centrifuge	g-force: 2000g Time: 10 minutes. Temperature: room temperature (RT).
Storage	
Register	Register the microtubes in the Biobank Information Management System (BIMS) and attach a cryovial label.
Aliquotation	Store the biomaterial in aliquots of minimal 0.5 ml to a maximum of 6 aliquots. If there is biomaterial left over add it to the 6 aliquots.
Type of tube	2 ml polypropylene microtube and screw-top with O-ring. GREI722301UMC and GREI368380UMC or equivalent.
Temperature	-80°C
Miscellaneous	
Sterile preparation	For sterile preparation make aliquots in the Biosafety Cabinet class 2 and follow the instructions in SOP 045014. Use sterile pipets (Greiner. nr 740365) and tubes for making the aliquots (Sarstedt. nr. 72694006)

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 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

- Hemolytic, icteric and lipemic samples can influence the analysis and deviations should be documented.
- Serum gel tubes provide a better separation than tubes without gel but for measurement of medications levels they are not recommended. There is a possibility of adsorption of lipophilic substances to the gel as described for some drugs including steroids.

5. Comments

- NEN-EN-ISO 23118 recommends that blood for metabolomic purposes should be collected after a minimum of 8 hours fasting. The collectors should specify and document in the clinical data if blood is collected under fasting or non-fasting conditions.
- For specific diagnostic tests validated in the Radboudumc under ISO15189 check the recommendations for the collection tube, pre analysis and stability in the eLabgids.

6. Relevant documents

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

link	Titel
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 – Radboud Biobank
Qdoc 015297	Bloedafname RLD: veneus en capillair
Link	eLabgids