



CHAIN PB-SAM BLOOD PROCESSING SOP

CHN PB-SAM 004: CHAIN PB-SAM BLOOD PROCESSING SOP

Purpose

The purpose of this SOP is to describe the standard procedures involved in processing and storing of study blood (EDTA for Plasma separation) sample after the sample has been delivered to the laboratory.

Responsibility

This SOP applies to any study laboratory staff. It is the responsibility of those users to follow the guidelines stipulated herein.

The Principal Investigator (through the study coordinator when applicable) retains the overall responsibility of implementation of these standard procedures.

The study laboratory coordinator is responsible for answering questions you may have about the content of this SOP and any other relevant study documentation. Please contact that the study laboratory coordinator through your site coordinator. Main CHAIN PB-SAM laboratory coordinator: Caroline Tigoï (email: ctigoï@kemri-wellcome.org) or (rmusyimi@kemri-wellcome.org).

Abbreviations/Definitions

PI Principal Investigator

EDTA Ethylene Diamine Tetra Acetic Acid

CRF Case Record Form

SOP Standard Operating Procedure

RPM Revolutions per Minute

Materials

1. EDTA purple tops (3 mls)
2. Sample storage vials – Nunc 1.8 ml cryotubes
3. Pipettes 200 µl and 1ml
4. Pipette tips 200µl and 1ml tips
5. -80 freezer
6. Temperature controlled centrifuge machine
7. Nalgene cryobox system 100 (10 x 10 boxes)
8. DNase/RNase free filter 200µl tips

Methods

1.0 General considerations

- 1.1 Samples collected from patients in this study will be for study-specific analyses.
- 1.2 Correct specimen collection bottles and correct request forms must always be used and verified at each collection.
- 1.3 Ensure all samples should be labelled with the Country code, site code, collection time-point code, (see Site Specific Collection Schedule (appendix 7.2), specimen type, patient and date of collection. For example: **10-A0-P1-XXX-12/10/2014**. For sample type, P=



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plasma from EDTA tube.

- 1.4 Keep samples on ice, with ice packs at all times.
- 1.5 For EDTA Plasma blood, make 4 aliquots of plasma for storage.
- 1.6 If limited amount of sample is collected, P1 and P2 have priority.
- 1.7 There should be a minimum of 300 µl of sample per aliquot before introducing a new aliquot. For example, if there is 500µl of EDTA plasma, put 250 µl in P1 and 250 µl in P2. If sufficient sample divide into two even aliquots.
- 1.8 Store each aliquot in separate 2-inch-high Nalgene system 100 plastic freezer boxes. The idea is that sample aliquots go to specific analytic sites for the specific analyses and are separated at this stage to facilitate an efficient pre-transportation process.
- 1.9 Each freezer box should be labeled on the top and on the side. The label should contain a unique number letter combination (see sample freezer box storage log – Appendix 7.4).
- 1.10 Purposes of the samples are for later investigation on biochemistry, immune and metabolic markers.
- 1.11 Gloves must be worn at all times when handling specimens. This includes during removal of the rubber stopper from the blood tubes, centrifugation, pipetting, disposal of contaminated tubes, and cleanup of any spills. Tubes, needles, and pipets must be properly disposed of in biohazard containers, in accordance with institutional requirements.
- 1.12 The time between arrival at the laboratory and freezing (dry ice, liquid nitrogen or -80 °C freezer storage) should be maximally 60 minutes. This will be monitored very closely for every site and any deviation on sample transportation and processing time will be communicated. Prolonged delays of sample storage will compromise the integrity of the sample affecting the quality of lab results and will not be included in data analysis. Temporary storage at -20°C is not allowed.

2.0 sample rejection criteria

The following sample rejection criteria will be enforced.

- 2.1 Insufficient of < 300 µl - Reject and notify lab manger and clinical team. Fill in sample rejection form
- 2.2 Hemolysed EDTA sample – Store but comment in CRF
- 2.3 Clotted blood - Reject and notify lab manger and clinical team. Fill in sample rejection form
- 2.4 Incomplete data – Notify clinical team to complete metadata
- 2.5 Missing sample - notify lab manager or clinical team
- 2.6 Two samples with the same specimen number on tube but different numbers in CRF and the vice versa – Reject, discard and notify lab manger and clinical team. Fill in sample rejection form.


3.0 Sample shipment log and registration

- 3.1 At the laboratory where samples are being processed and divided into aliquots, the Sample shipment log MUST be filled out.
- 3.2 Record time of receiving of sample and freezing of samples on the Sample Shipment Log.
- 3.3 Record in the log if less than the optimal amount of sample is stored (see appendix 7.2) and document the amount of volume stored as specific aliquots.

3.1 Document history



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Version 1	Author	Approved by	Signature	Dated
1.02 CHAIN PB-SAM Blood sample processing SOP	Caroline Tigoi	Robert Bandsma		24-01-2021

4.0 Site training record

All sites are required to maintain a master copy of this SOP that documents the site staff that have been trained on this SOP.

Document History				
Version No.	Trained staff initials	Signature of trained staff	Date	Trainer's Initials
1.01	KDT	Example row	1 st Jan 2016	DM

5.0 References



6.0 Appendices

Appendix 6.1: Diagram Sample Processing

