CHAIN 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.

Abbreviations/Definitions

EDTA Ethylene Diamine Tetra acetic Acid
CRF Case Record Form
SOP Standard Operating Procedure
RPM Revolutions per Minute

Materials

1. EDTA pink tops (2 mls)
2. Sample storage vials – Nunc 2 ml cryotubes
3. Pipettes 200 µl and 1ml
4. Pipette tips 200 µl 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: **PB-SAM-10-001-A0-P-XXX-12/10/2021**. For sample type, P= plasma from EDTA tube.
1.4 Keep samples on ice, with ice packs at all times.
1.5 For EDTA Plasma blood, make 3 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 250 µl of sample per aliquot before introducing a new aliquot.

For example, if there is 500 µl 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 shipment log and registration

2.1 At the laboratory where samples are being processed and divided into aliquots, the Sample shipment log MUST be filled out.

2.2 Record time of receiving of sample and freezing of samples on the Sample Shipment Log.

2.3 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

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

4.0 Site training record

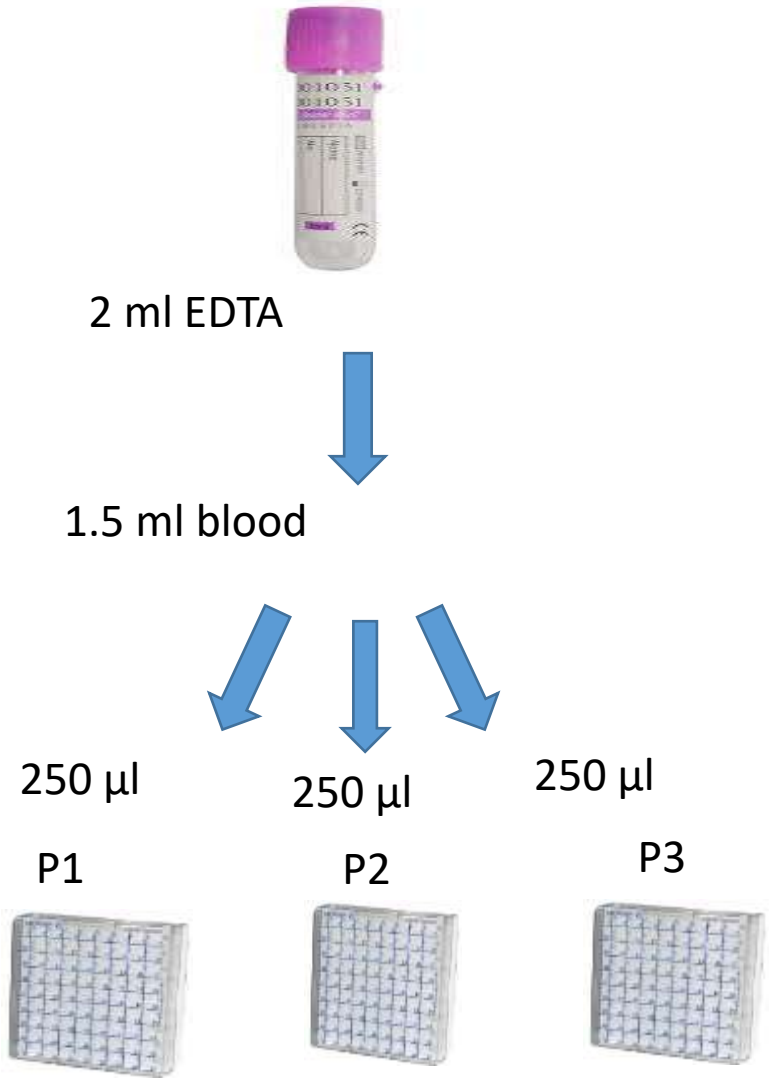
All sites are required to maintain a master copy of this SOP that documents the site staff that have been trained on this SOP.

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

5.0 References

6.0 Appendices

Appendix 6.1: Diagram Sample Processing



SITE NAME:		STUDY NAME:			POINT OF ORIGIN:	
DESTINATION:		PI NAME:			DATE:	
Subject ID	Specimen Type*	Specimen ID (Barcode number)	Visit No**	Date Collected	Time collected	Comments

Appendix 6.2 Sample Shipment Log

SHIPPED BY_____**DATE**_____ **(DD/MM/YYYY) TIME**_____ **TEMP:** _____

RECEIVING _____**DATE**_____ **(DD/MM/YYYY) TIME**_____**TEMP:**_____

STORED BY_____**DATE**_____ **(DD/MM/YYYY) TIME**_____

Visit Numbers: A0**-Admission; **D0**-Discharge; **D21**-Day 21; **D60** - Day 60, **RA –** Readmission
Specimen Type*: Stool (F1, F2, and F3), Blood (Plasma) or Rectal Swab (R1)

Appendix 6.3 Sample Collection Schedule

	ADMISSION (and within 72 hours)	DAILY IN HOSPITAL	DISCHARGE	Day 21	Day 60	READMISSION
Blood sample	X			X		X
Rectal swab/stool	X		X	X	X	X
12 hourly capillary blood gas & lactate (days 1-5 only)*		X				
Hydrogen breath test**	X			X		

* Kenya and Bangladesh only
** Malawi and Uganda only

Appendix 7.4: Sample freezer box storage log

CHAIN PLASMA samples Box 1	A	B	C	D	E	F	G	H	I
1	1-1-1740 124322 02/09/2016	1-1-1741 126234 02/09/2016	1-1-1743 122309 02/09/2016	1-1-1744 126241 02/09/2016	1-1-1745 126242 02/09/2016	1-1-1748 123838 03/09/2016	1-1-1749 125523 03/09/2016	1-1-1747 126258 04/09/2016	1-1-1750 126259 04/09/2016
2	1-1-1752 126263 04/09/2016	1-1-1753 125133 04/09/2016	1-1-1751 121934 05/09/2016	1-1-1754 126267 05/09/2016	1-1-1756 126273 05/09/2016	1-1-1757 126271 05/09/2016	1-1-1755 123610 05/09/2016	1-1-1760 126274 05/09/2016	1-1-1758 126287 06/09/2016
3	1-1-1769 125887 06/09/2016	1-1-1770 125283 06/09/2016	1-1-1762 126279 07/09/2016	1-1-1763 124053 07/09/2016	1-1-1765 122460 07/09/2016	1-1-1764 124224 07/09/2016	1-1-1759 125318 08/09/2016	1-1-1767 125766 08/09/2016	1-1-1768 125755 08/09/2016
4	1-1-1775 125876 08/09/2016	1-1-1771 126320 08/09/2016	1-1-1772 126322 08/09/2016	1-1-1773 126323 09/09/2016	1-1-1774 126351 09/09/2016	1-1-1776 126319 09/09/2016	1-1-1777 125860 09/09/2016	1-1-1778 126321 09/09/2016	1-1-1780 126233 09/09/2016
5	1-1-1766 125474 10/09/2016	1-1-1783 123904 10/09/2016	1-1-1784 126412 10/09/2016	1-1-1785 126409 10/09/2016	1-1-1786 126415 11/09/2016	1-1-1787 124932 11/09/2016	1-1-1788 123644 11/09/2016	1-1-1789 126416 11/09/2016	1-1-1790 126417 11/09/2016
6									
7									
8									
9									

SOP AWARENESS LOG

I, the undersigned below, hereby confirm that I am aware that the accompanying SOP is in existence from the date stated herein and that I shall keep abreast with the current and subsequent SOP versions in fulfilment of Good Clinical Practice (GCP).

Number	Name	Signature	Date (dd/mmm/yyyy)
1.			
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