Purpose

The purpose of this SOP is to describe the standard procedures involved in collection and transport to the laboratory of study blood samples. This SOP applies inpatients and community participants.

Responsibility

This SOP applies to nursing staff, study clinicians and fieldworkers of study sites who will be undertaking the collection of blood samples. It is the responsibility of the 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
FBC	Full Blood Count
RDT	Rapid Diagnostic Test
DBS	Dry blood spot
SOP	Standard Operating Procedure
PID	Patient ID

Required material

- CRF appropriate to time point
- Site Specific Sample Collection Schedule
- Study Sample Collection Log
- EDTA purple/pink tops (500 µl and 2 ml)
- Red top serum tubes (2 ml)
- Blood culture tubes (if required)
- Filter paper (if required)
- Disposable gloves
- Alcohol swabs, isopropyl alcohol/ spirit
- Tourniquet
- Vacutainer holders
- Disposable needles ± Vacutainer (19-23 G)
- 2 ml and 5 ml syringes
- Cotton balls/ dry swabs
- Sharps disposal container
- Ice Packs

Methods

1.0 General considerations

1.1 Samples collected from patients are study and site specific.

1.2 The admission sample should ideally be taken within 30 minutes of the patient being assessed in the emergency department and deemed eligible for the study, however if this is not possible due to emergency treatment the sample should be taken within 30 minutes after the child has been cleared for transport to the ward.

1.3 Correct specimen collection bottles must always be used and verified at each collection (see CHAIN Site Specific Collection Schedule (Appendix 7.2)).

1.4 If there is limited amount of blood serum tubes (red top) have the highest priority and the EDTA (purple top) the second highest priority. If there is only sufficient blood for one EDTA tube, please only use the 2 ml EDTA tube.

1.5 Mark on the Study Sample Collection Log and CRF that the samples was taken and if not possible also indicate this.

1.6 Blood draws can be performed by the clinic/research nurse, clinical officer or clinician. All research blood draws should ideally be timed with clinical blood draws where possible to reduce the number of venipuncture's to the child.

1.7 Universal precautions and Occupational Safety and Health Administration and institutional requirements (http://www.osha.gov/SLTC/biologicalagents/index.html) should be followed.

1.8 If any study staff are pricked by a used needle or are otherwise concerned that they have been exposed to blood borne pathogens they should review the post-exposure prophylaxis SOP (CHN30) in addition to the Institutional Infection Control Policy.

2.0 Blood draw

2.1 Venipuncture and blood draw should be done in a procedure room when possible.

2.2 The phlebotomist should wear disposable gloves and use aseptic technique during phlebotomy.

2.3 New sterile, single use needles, syringe, collection bottles or Vacutainer tubes are to be used for each blood draw, and after completion needles must be properly disposed of in a puncture resistant container.

2.4 Do not prepare tubes for more than one patient at a time.

2.5 Before the procedure, check if the patient has consented to international shipping. If not, please add a red sticker to the blood collection tubes. This information will be on the front of the patient file.

2.6 Verify that this is the correct participant.

2.7 The caregiver should be present for the blood draw. Ideally the child should be on the caregiver's lap and blood should be drawn from the hand or antecubital fossa. Position the child so that the arm is behind the caregiver and the caregiver is holding the child securely.

2.8 A second member of the research or clinical team should be present to assist, to prevent the child from moving the limb away and to distract and calm the child if necessary.

2.9 Explain the blood drawing procedure to the family and patient and reassure them that it is a safe procedure, but it may cause some distress.

2.10 Wash hands with soap and water

2.11 Palpate and choose a vein. The preferred sites for phlebotomy are the median antecubital

veins of the upper extremity, however, if other veins are apparent and appear more accessible these may be used. A tourniquet may be used to transiently distend veins prior to drawing blood. Do not leave the tourniquet for more than 3 minutes.

2.12 Femoral vein blood draw is not advised unless being used for clinical bloods.

2.13 Thoroughly disinfect the phlebotomy site by swabbing the skin in small outward circles with an alcohol swab. Do not touch the prepared puncture site with your fingers after disinfecting the skin.

2.14 Using aseptic technique, insert the needle into the vein. Butterfly needles with a 10ml syringe are advised as these cause less damage to the vein and also increase the success of drawing blood as the vein is less likely to collapse. Alternatively blood can be dripped from the cannula directly into the tubes.

2.15 **Take blood and put into different blood collection tubes with volumes according to the Site Specific Collection Schedule**

2.16 After drawing, mix the blood in tubes containing additives by inverting the tubes several times.

2.17 The tubes containing additives (EDTA, purple top) must be mixed well as soon as possible either during collection or immediately after. You should mix the tube 8-10 times by inverting the tube completely. Do not shake the tube as this may cause hemolysis and foaming.

2.18 If a blood culture is required for research purposes, collect this sample last. Please be familiar with the CHAIN blood culture SOP (CHN 71). If you are using the same syringe for collection of blood for culture and transfer into EDTA/serum tubes, replace the needle for transfer into the blood culture bottle.

2.19 If a dried blood spot is required, see blood spot SOP (CHN 32).

2.20 The finger or heel prick technique is advised from admission when blood glucose and HIV testing are required. For advice on the finger/heel prick technique see the blood glucose SOP (CHN 34). It is also acceptable to remove a minimal amount of blood from a red top serum tube to create a blood spot.

2.21 If an HIV test is required, please be familiar with the PITC SOP (CHN 33).

2.22 If blood glucose test is required please be familiar with the blood glucose SOP (CHN 34).

2.23 Note: All blood gases will be capillary gases and should be taken according to institutional protocol. The only stipulation is that all gases must analyzed within 15 minutes of being taken.

2.24 Immediately after drawing the required blood samples, release the tourniquet if used. Remove the needle from the vein, cover the puncture site with a cotton swab, and hold until adequate hemostasis is visible.

2.25 Blood tubes should be labelled with the Country code, site code, collection time-point, (see Site Specific Collection Schedule (appendix 7.2)), specimen type, Participant ID and date of collection. For example: **10-001-A0-DBS-XXX-12/10/2014**.

2.26 Do not let samples sit at room temperate for more than 15 minutes after collection and keep samples on ice/with ice pack in water until processing/storage.

2.27 Samples should be transported and arrive at the laboratory within 30 minutes after collection.

3.0 Sample log and registration

3.1 All samples collected from a participant MUST first be logged in the Study shipment Log and the appropriate CRF, available in the ward/ study office.

3.2 Record time of collection on the Sample shipment log.

4.0 References

F-75 Trial Sample Collection SOP
Toto Bora Blood Collection SOP

5.0 Document history

Version	Author	Approved by	Dated
1.03 **CHAIN BLOOD COLLECTION SOP (MASTER) CHN 28**	Robert Bandsman	Caroline Tigoi	10/11/2016
1.04 **CHAIN BLOOD COLLECTION SOP (MASTER) CHN 28**	Robert Bandsman	Caroline Tigoi	06/01/2017

6.0 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

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

7.0 Appendices

7.1 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**_____

KEY

Visit Numbers:**

Visit Numbers: A0**-Admission; **A2**- Day 2; **A5** - Day 5; **D0**-Discharge; **D1**-Day 45; **D2** - Day 90, **D3** - Day 180, **RA** – Readmission **AD**- Deterioration and **CP**- Community participant

Specimen Type*: Stool (F1, F2, and F3), Blood (Whole blood, Plasma, Serum or DBS) or Rectal Swab (R1and R2)

7.2 Site Specific Collection Schedule

Site Specific Sample collection Schedule
Migori

Tube	Volumes									
	Admission	D 2	D 5	Discharge	D 45	D 90	D 180	Readmission	Deterioration	Community participant
Time point code	AO	A2	A5	D0	D1	D2	D3	RA	AD	CP
EDTA 1 (Purple)	0.5 ml			0.5 ml	0.5 ml	0.5 ml	0.5 ml	0.5 ml		0.5 ml
EDTA 1 (Purple)	1.5 ml	1.5 ml	1.5 ml	1.5 ml				1.5 ml	0.5 ml	1.5 ml
Serum 1 (Red)	0.5ml			0.5ml				0.5ml		
Serum 1 (Red)	1.5 ml			1.5 ml	1.5 ml	1.5 ml	1.5 ml	1.5 ml		1.5 ml
DBS	1			1				1		1
Blood glucose	1							1	1	
HIV RDT	1									1
Malaria RDT	1							1	1	
Rectal swabs	2			2	2	2	2	2		2
Whole stool	1			1	1	1	1	1		1
Dual sugar test				If selected						
Urine				1			1			1

Tube	Volumes									
	Admission	D 2	D 5	Discharge	D 45	D 90	D 180	Readmission	Deterioration	Community participant
Time point code	AO	A2	A5	D0	D1	D2	D3	RA	AD	CP
EDTA 1 (Purple)	0.5 ml			0.5 ml	0.5 ml	0.5 ml	0.5 ml	0.5 ml	0.5 ml	0.5 ml
EDTA 1 (Purple)	1.5 ml			1.5 ml				1.5 ml	0.5 ml	1.5 ml
Serum 1 (Red)	0.5 ml			0.5 ml				0.5 ml		
Serum 1 (Red)	1.5 ml			1.5 ml	1.5 ml	1.5 ml	1.5 ml	1.5 ml		1.5 ml
Blood culture	2 ml							2 ml	2 ml	
DBS	1			1				1		1
Blood glucose	1							1		
HIV RDT	1								1	1
Malaria RDT	1							1	1	
Rectal swabs	2			2	2	2	2	2		2
Whole stool	1			1	1	1	1	1		1

Tube	Volumes									
	Admission	D 2	D 5	Discharge	D 45	D 90	D 180	Readmission	Deterioration	Community participant
Time point code	AO	A2	A5	D0	D1	D2	D3	RA	AD	CP
EDTA 1 (Purple)	0.5 ml			0.5 ml	0.5	0.5	0.5	0.5 ml		0.5 ml
EDTA 1 (Purple)	1.5 ml			1.5 ml				1.5 ml	0.5 ml	1.5 ml
Gas/lactate	0.14 ml	0.14 ml	0.14 ml	0.14 ml					0.14	
Blood Culture	2 ml							2 ml	2 ml	
Serum 1 (Red)	0.5ml			0.5ml				0.5ml		
Serum 1 (Red)	1.5 ml			1.5 ml	1.5 ml	1.5 ml	1.5 ml	1.5 ml		1.5 ml
Sodium Heparin (Green)		2 ml		2 ml	2 ml	2 ml	2 ml			2ml
DBS	1			1						1
Blood glucose	1							1		
HIV RDT	1									1
Malaria RDT	1							1	1	
Rectal swabs	2			2	2	2	2	2		2
Whole stool	1			1	1	1	1	1		1

Tube	Volumes									
	Admission	D 2	D 5	Discharge	D 45	D 90	D 180	Readmission	Deterioration	Community participant
Time point code	AO	A2	A5	D0	D1	D2	D3	RA	AD	CP
Samples sent to Dr. Joloba's laboratory										
EDTA 1 (Purple)	0.5 ml			0.5 ml			0.5 ml	0.5 ml		0.5 ml
EDTA 2 (Purple)	1.5 ml			1.5 ml			1.5 ml	1.5 ml		1.5 ml
Serum 1 (Red)	1.5 ml			1.5 ml			1.5 ml	1.5 ml		1.5 ml
DBS	1			1			1	1		1
Rectal swabs	2			2	2	2	2	2		2
Whole stool	1			1	1	1	1	1		1
Point of Care Testing										
Blood glucose	1							1	1	
HIV RDT	1									1
Malaria RDT	1							1		1
Samples sent to CORE lab										
CBC with diff	0.5 ml	0.5 ml		0.5 ml	0.5 ml	0.5 ml	0.5 ml	0.5 ml	0.5 ml	0.5 ml
Chemistries	1 ml			1 ml				1 ml	1 ml	1 ml
Samples below sent to JCRC Immunology lab										
Sodium Heparin (Green)		1.5 ml		1.5 ml*	1.5 ml	1.5 ml	1.5 ml*			1.5 ml
CPT (Blue/black)		4 ml max		4 ml max*	4 ml max	4 ml max	4 ml max*			4 ml max
Urine		Up to 4 ml**			Up to 4 ml‡		Up to 4 ml‡			
For children eligible for TB sub study only—Joloba TB lab										
Induced sputum			Send X 1 during hospitalization					Send X 1 during hospitalization		
Whole stool			Send X 1 during hospitalization					Send X 1 during hospitalization		

*may be deferred so that total volume of blood for research does not exceed 1 ml/kg. Do not collect on Friday, Saturday, or Sunday

**for children eligible for TB sub-study only

‡for children on active TB treatment only

Tube	Volumes									
	Admission	D 2	D 5	Discharge	D 45	D 90	D 180	Readmission	Deterioration	Community participant
Time point code	AO	A2	A5	D0	D1	D2	D3	RA	AD	CP
EDTA 1 (Purple) CBC with diff	0.5 ml	0.5 ml		0.5 ml	0.5 ml	0.5 ml	0.5 ml	0.5 ml	0.5 ml	0.5 ml
EDTA 1 (Purple)	1.5 ml	1.5 ml		1.5 ml				1.5 ml	1.5 ml	1.5 ml
Blood culture*	2ml	2ml						2ml	2ml	
Serum 1 (Red)	2.0 ml	2.0 ml		2.0 ml	1.5 ml	1.5 ml	1.5 ml	2.0 ml	0.5 ml	1.5 ml
DBS	1	1		1				1		1
Blood glucose	1	1						1		
HIV RDT	1									1
Rectal swabs	2	2		2	2	2	2	2		2
Whole stool	1	1		1	1	1	1	1		1
Malaria RDT	1							1		

*only if clinically indicated (i.e. if child has symptoms of sepsis)

CHAIN BLOOD COLLECTION SOP (MASTER)

Civil Hospital

Tube	Volumes									
	Admission	D 2	D 5	Discharge	D 45	D 90	D 180	Readmission	Deterioration	Community participant
Time point code	AO	A2	A5	D0	D1	D2	D3	RA	AD	CP
EDTA 1 (Purple)	0.5 ml			0.5 ml	0.5 ml	0.5 ml	0.5 ml	0.5 ml	0.5 ml	0.5 ml
EDTA 1 (Purple)	1.5 ml			1.5 ml				1.5 ml	0.5 ml	1.5 ml
Gas/lactate	0.14 ml	0.14 ml	0.14 ml	0.14 ml					0.14	
Blood culture	2ml							2ml	2ml	
Serum 1 (Red)	0.5 ml			0.5ml			0.5ml	0.5ml		0.5ml
Serum 1 (Red)	1.5	1.5		1.5			1.5	1.5		1.5
DBS	1			1						1
Blood glucose	1							1		
Blood gas	0.1 ml	0.1 ml	0.1 ml	0.1 ml				0.1 ml		
HIV RDT	1									1
Rectal swabs	2			2	2	2	2	2		2
Whole stool	1			1	1	1	1	1		1
Dual sugar test				If selected						
Malaria smear	1							1		1
Urine storage				1			1			1
	TB SUB-Study									
Gastric/ Bronchial Aspirate	1									
Stool Gene xpert	1									
Urine storage	1					1	1			

Tube	Volumes									
	Admission	D 2	D 5	Discharge	D 45	D 90	D 180	Readmission	Deterioration	Community participant
Timepoint code	AO	A2	A5	D0	D1	D2	D3	RA	AD	CP
EDTA 1 (Purple)	0.5 ml			0.5 ml	0.5 ml	0.5 ml	0.5 ml	0.5 ml	0.5 ml	0.5 ml
EDTA 1 (Purple)	1.5 ml			1.5 ml				1.5 ml	0.5 ml	1.5 ml
Serum 1 (Red)	0.5 ml			0.5 ml	0.5 ml	0.5 ml	0.5 ml	0.5 ml	0.5 ml	
Serum 1 (Red)	1.5ml			1.5 ml	1.5 ml	1.5 ml	1.5 ml	1.5 ml		1.5 ml
DBS	1			1						1
Blood culture	1							1	1	
Blood glucose	1							1	1	
HIV RDT	1									1
Rectal swabs	2			2	2	2	2	2		2
Whole stool	1			1	1	1	1	1		1
Malaria RDT	1							1		

Tube	Volumes									
	Admission	D 2	D 5	Discharge	D 45	D 90	D 180	Readmission	Deterioration	Community participant
Timepoint code	AO	A2	A5	D0	D1	D2	D3	RA	AD	CP
EDTA 1 (Purple)	0.5 ml			0.5 ml				0.5 ml		0.5 ml
EDTA 1 (Purple)	1.5 ml			1.5 ml				1.5 ml	0.5 ml	1.5 ml
Serum 1 (Red)	0.5ml			0.5ml	0.5ml	0.5ml	0.5ml	0.5ml	0.5ml	
Serum 1 (Red)	1.5 ml			1.5 ml	1.5 ml	1.5ml	1.5 ml	1.5 ml		1.5ml
DBS	1			1						1
Blood glucose	1							1	1	
Blood culture	1							1		
Blood gas	0.1 ml	0.1 ml	0.1 ml	0.1 ml				0.1 ml		
HIV RDT	1									1
Rectal swabs	2			2	2	2	2	2		2
Whole stool	1			1	1	1	1	1		1
Malaria RDT	1							1		