CHN26: CHAIN Rectal Swab Collection SOP V1.04

Purpose

The purpose of this SOP is to describe the standard procedures involved in collection and transport to the laboratory of rectal swabs.

Responsibility

This SOP applies to nursing staff, study clinicians and fieldworkers of study sites who will be undertaking the collection of rectal swabs. 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

CRF	Case Record Form
SOP	Standard Operating Procedure
PID	Positive Identification Labels

Required material

- Pens/ markers
- Biohazard bins and bags (red autoclavable or equivalent)
- Gloves (disposable)
- CHAIN PID labels
- Plastic bags (zip lock) for specimen transport
- Ice packs (reusable)
- Shipping/ Mailing containers/ cool box for specimen transport
- Small clean dry plastic bags for specimen collection in clinic (if necessary)
- Shipping thermometers
- Paper towels/ tissue rolls or equivalent
- 1 Pediatric Floqswab rectal swabs with plain containers
- 2 Pediatric Faecal Swab kit (42028S) with Cary Blair containers (one for sites NOT performing stool culture)

Methods

1.0 General considerations

1.1 Samples collected from patients are study and site-specific, consult the sample collection schedule prior to each collection

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

1.3 Wear proper protective equipment, including gloves and lab coats.

1.4 Appropriate collection devices, specimen containers, and transport media must be used to ensure optimal recovery of microorganisms and storage.

1.5 Personnel are responsible for collecting specimens and disposing in proper containers such as biological waste bags in biohazard bins. The biohazard waste must then be autoclaved and/ or incinerated.

1.6 Handle all specimens with care and treat them as potentially infectious material.

1.7 All should be shipped in containers labelled with biohazard symbol at any given time.

1.8 The timing of rectal swab collection is critical to the study's success:

1.8.1 Admission sample: Collect rectal swabs immediately upon enrolment. This should preferably before administration of the child's first antibiotics in hospital. Work with your site's clinical team to achieve this. Rectal swabs maybe obtained before formal enrolment paper work is complete, but must be after Verbal consent. Written consent should be obtained thereafter as soon as it is possible.

1.8.2 Discharge: When the child is formally cleared for discharge by the medical team collect the rectal swabs as soon as possible.

1.8.3 Follow-up and community participants: Collect rectal swabs immediately (see rectal swab SOP (CHN26)) upon presentation at clinic.

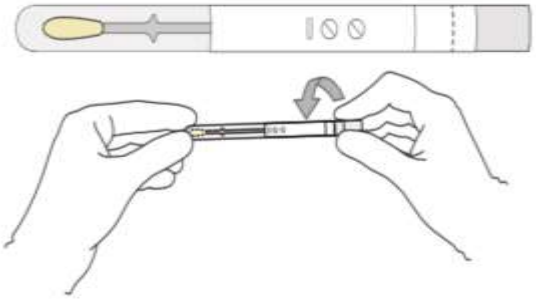
1.9 At all-time points it is very important that you record the time at which rectal swabs were obtained. Record this information on the relevant CRFs.

2.0 Collection of stool sample via rectal swab

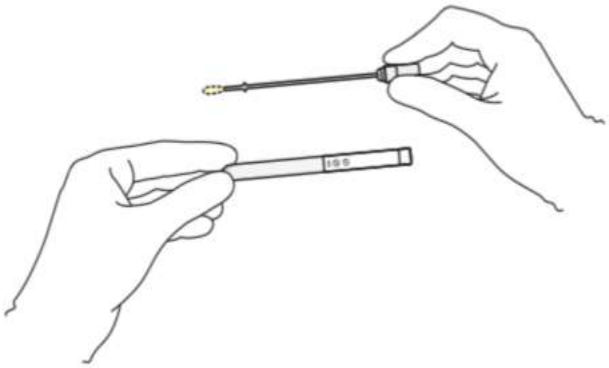
2.1 Before the procedure label the rectal swab tube, ensure that if the patient has not consented to international shipping a red sticker is used. This information will be on the front of the patient file. Rectal swab tubes should be labelled with the Country code, site code, collection time point, (see Site Specific Collection Schedule (appendix 7.2), specimen type (R1 and R2), Patient ID and date of collection. For example: **10-001-A0-R1-XXX-12/10/14**. Ensure that a red sticker is used for those who have not consented to international shipping).

2.2 Explain the procedure to the caregiver, mention that it is not a painful procedure but maybe a little uncomfortable for the child.

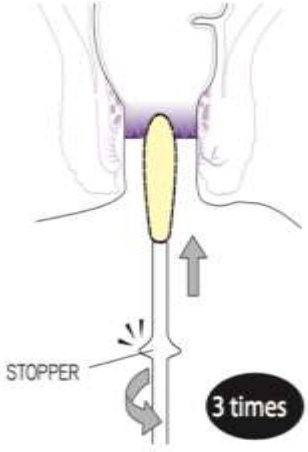
2.3 Using gloves, hold the plastic tube with both hands. Twist the white handle anti clockwise to break the seal, remove the swab from the tube without touching the swab tip, and place tube on a clean surface.



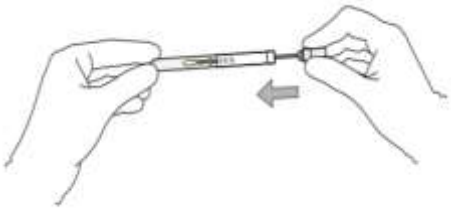
2.4 Remove the swab from the tube



2.5 With the participant in a comfortable fetal position lying on his or her left side (left lateral position), gently insert the swab into the anal canal until it reaches the “stopper”, or until resistance is felt. Rotate the swab 3 times, then slowly remove it. Note: swabbing the rectum may cause the child to have a bowel movement.



2.6 Insert the swab in the tube and close tightly



2.7 This first rectal swab is labelled as R1, and will be used for the molecular detection of pathogens in the stool. The rectal swab with plain container should be used for sample R1.

2.8 If the child passes whole stool during the rectal swab procedure collect the whole stool sample by using a clean spoon or wooden tongue depressor transfer the whole stool into containers as instructed in the whole stool collection SOP (CHN28).

2.9 Samples should be transferred into appropriate cooling containers as soon as possible from collection, not to exceed 1 hour.

2.10 Repeat this procedure to collect samples R2. Sites performing culture on site i.e. Kilifi, Mbagathi, Migori, Dhaka, Matlab and Karachi should use the Faecal Swab kit (42028S) with carry-blair to collect and transport the swab to the lab.

For sites not performing stool cultures (I.e. Uganda and Blantyre), R2 should be collected, then the end of the swab snipped with sterile scissors and placed directly into a cryovial containing freezing mixture (See SOP CHN59). Note that the freezing mixture must be kept in a refrigerator or freezer box prior to use.Place all swabs in a cool box for temporary storage at 2-8°C, send to the Laboratory Technician for processing. Maximal time to arrive at the laboratory is 30 minutes.

2.11 The date and time of sample collection are recorded in the Enrolment Form.

3.0 Sample log and registration

3.1 All samples collected from a participant MUST first be logged in the study Sample log form (appendix 7.1), available in the ward/ study office.

3.2 The following other log forms/ registers for samples are available:

a. Lab request form
b. Collection log form

4.0 References

Toto Bora Stool specimen collection SOP

5.0 Document history

Version 1	Author	Approved by	Dated	SOP No:
1.03 **CHAIN Rectal swab collection**	Kirk tickellk	Caroline Tigoi	10/11/2016	**CHN26**
1.04 **CHAIN Rectal swab collection**	Kirk tickellk	Caroline Tigoi	06/01/2017	**CHN26**

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

7.0 Appendices

7.1Sample Shipment Log

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**

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 (Plasma, Serum or DBS) or Rectal Swab (R1 and 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)

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		