

# CHAIN WHOLE STOOL & RECTAL SWAB PROCESSING SOP

## CHAIN WHOLE STOOL & RECTAL SWAB PROCESSING SOP

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### Purpose

The purpose of this SOP is to describe the standard procedures involved in processing and storing of study whole stool samples and rectal swabs.

### 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 the study laboratory coordinator through your site lab-coordinator.

Main CHAIN laboratory coordinator: Caroline Tigoi (email: [ctigoi@kemri-wellcome.org](mailto:ctigoi@kemri-wellcome.org))

### Abbreviations/Definitions

SOP Standard Operating Procedure

### Materials

1. Fecal collection containers
2. Non-absorbent plastic surface
3. Wooden spatula
4. Patient Sample labels
5. Sample storage vials (2.0 ml)
6. -80 freezer
7. Polycarbonate freezer boxes

### Methods

#### 1.0 General considerations

- 1.1 Samples collected from patients in this study will be for study-specific analyses
- 1.2 Specimens collected for various tests
- 1.3 Correct specimen collection bottles and correct request forms must always be used and verified at each collection.
- 1.4 Ensure all samples should be labelled by Country code, site code, collection time point, (see Site Specific Collection Schedule (appendix 7.2), specimen type (F1, F2 or F3), Patient ID and date of collection. For example: **PB-SAM-10-001-A0-F1-XXX-12/10/14**. Add a red sticker to the tubes if caregivers do not consent to international shipping of samples.
- 1.5 Ensure that tubes marked with a red sticker are stored in a separate freezer box that is clearly labeled (Fecal not for shipment). These samples will be retained at the site as they have no consent for international shipping.
- 1.6 Keep samples on ice, with ice packs at all times.
- 1.7 For stool, storage cryovials should be at least 2/3 full (i.e. 1.5ml of stool).
- 1.8 If the volume of stool is insufficient, the aliquots F1 and F2 have priority.

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- 1.9 Store each aliquot in separate 2-inch polycarbonate (Nalgene 10 x 10 system) freezer box. Samples are destined for different analytic sites for specific analyses and are to be separated at this stage to facilitate an efficient pre-transportation process.
- 1.10 Each freezer box should be labeled on the top and on the side using printed cryo labels. The label should contain a unique number letter combination (see sample freezer box storage log – Appendix 7.3).

### 2.0 Whole Stool Processing

- 2.1 Ensure all fecal collection containers have been correctly labeled, by comparing the sample to the Sample Transportation Log.
- 2.2 Record time of receiving samples on the Sample Transportation Log. Stool collection pots should contain at least 5ml of stool. Record insufficient stool volume on the CRF.
- 2.3 Prior to aliquoting the samples, label the empty freezer storage vials with specific barcodes. The first two aliquots will be shipped internationally. These aliquots will be called F1 and F2. The final sample will be retained at the study site, and will be called F3.
- 2.4 Mix stool using a spatula before dividing it into the different aliquots.
- 2.5 Stool should be collected in fecal collection containers and separated using the wooden spatula or a plastic wire loop in 3 aliquots of at least 1.5 ml or 2/3 full of a cryovial (named F1, F2 & F3). If volume is insufficient, fill the first two tubes and label accordingly.
- 2.6 Ideally, stool samples should be stored at -80 degrees Celsius within 30 minutes after arrival at the laboratory. However, blood and rectal swabs can be processed prior to stool samples which may result in stool having a processing time of over 30 minutes. Due to challenges in obtaining stool on time, some samples may be collected in the community and delivered in the lab after 30 minutes of collection. Never discard a stool sample because the collection time or processing time has been too long. Record time of storage in the Sample Transportation Log and the CRF.

### 3.0 Rectal swab processing

- 3.1 Ensure all rectal swabs have been correctly labeled. By comparing the sample to the Sample shipment log.
- 3.2 Patient samples which arrive at the laboratory with a red sticker do not have consent for international shipping. Confirm with the study team that this sample is correctly labelled with the red sticker (i.e., the family has not consented to international shipping). All three aliquots, from these patients should be clearly labelled with a red cryo sticker confirming that they should not be shipped.
- 3.3 Rectal swabs R1 collected using a dry FLOQswab should be cut using a sterile disposable scissor or breaking the swab just below the shaft by bending and twisting it against the wall of a 2 ml cryotube and stored in -80 degrees Celsius within 30 mins of arrival at the laboratory. Record time of storage in the Sample Transportation Log.
- 3.4 Rectal swab R2 should be cut just below the shaft and put in 1ml of freezing mixture (See SOP CHN---) and should be stored up right in -80 degrees Celsius within 30 minutes of arrival at the laboratory. If R2 is being used for culture on site, then it will be transported in carry Blair available as a kit together with the swab and it should be cultured within 30 minutes of receipt in the laboratory (See CHN101).
- 3.5 All the isolates obtained after culture should be stored in – 80°C freezers (3 morphologically

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different isolates for E. coli and one each for other isolates). Each Isolate should be labeled with Country code, site code, Collection time point, Isolate name abbreviation as per the CHAIN reporting of microbiology results SOP – CHN:62 and KIDMs abbreviation codes (ECO unidentified with unique specimen IDs generated from KIDMs), Patient ID, and date of isolation. **PB-SAM-10-001-A0-ECO-XXX -12/10/14.**

### 4.0 Sample log and registration

- 4.1 At the laboratory the stool samples are divided into 3 aliquots and rectal swabs transferred to 2 ml cryotubes before storage. The Sample Transportation Log MUST be filled out. Complete this log immediately after the samples have been placed in the freezer
- 4.2 Record time of receiving of sample and freezing of samples on the Sample Transportation Log.

### 5.0 Document history

Version 1	Author	Approved by	Signature	Dated
1.02 <b>CHAIN Stool sample processing</b>	Caroline Tigoï	Robert Bandsma		24-01-2021

### 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	1 <sup>st</sup> Jan 2016	DM

### 7.0 Appendices

#### 7.1 Sample shipment log

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SHIPPED BY \_\_\_\_\_ DATE \_\_\_\_\_ (DD/MM/YYYY) TIME \_\_\_\_\_ TEMP: \_\_\_\_\_

RECEIVING \_\_\_\_\_ DATE \_\_\_\_\_ (DD/MM/YYYY) TIME \_\_\_\_\_ TEMP: \_\_\_\_\_

SITE NAME:		STUDY NAME:			SAMPLE COLLECTION POINT:	
RECEIVING LAB:		PI NAME:			DATE:	
Subject ID	Specimen Type*	Specimen ID (Barcode number)	Visit No**	Date Collected	Time collected	Comments

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 7.2: Site Specific Collection Schedule

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

\* Kenya and Bangladesh only

\*\* Malawi and Uganda only

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## Appendix 7.3: Sample freezer box storage log

CHAIN Stool 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									

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## 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.			
2.			
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