






Pancreatic Enzymes and Bile Acids: A Non-Antibiotic approach to Treat Intestinal Dysbiosis in Acutely Ill Severely Malnourished Children

Study Specific Procedure			SSP No: LA08 Version No: 1.0 Supersedes: None Effective Date: 21 st October 2021
Title: Preparation Freezing Mixture			
	NAME	SIGNATURE	DATE
PREPARER	Robert Musyimi		30 th September 2021
Q.A. AUTHORITY	Aisha Bwika		16 th October 2021
APPROVING AUTHORITY	Robert Bandsma		20 th October 2021

APPROVED

1.0 PURPOSE / INTRODUCTION:

The purpose of this SOP is to describe the standard procedures involved in preparation and QC of freezing mixture used to store wet rectal swab (R2) samples

2.0 SCOPE / 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 PB-SAM laboratory coordinator: Caroline Tigo (email: ctigo@kemri-wellcome.org or rmusyimi@kemri-wellcome.org).

3.0 DEFINITIONS /ABBREVIATIONS:

3.1 SOP Standard Operating Procedure

3.2 PI Principal Investigator

3.3 FM Freezing mixture

3.4 QC Quality control

3.5 R2Rectal swab (wet)

4.0 MATERIALS

4.1 -80oC freezer

4.2 Nunc vial

4.3 Tryptone Soy Broth, Oxoid CM0129

4.4 Glycerol, Sigma G5516

5.0 METHODOLOGY:

5.1 General considerations

5.1.1 FM prepared using tryptone soya broth and 15% is a standard media for preservation of micro-organisms in rectal swabs and culture.

5.1.2 This is a general-purpose medium, containing two peptones, is suitable for the cultivation of both aerobes and anaerobes.

5.1.3 The media must be sterilized at 1210 C for 15 minutes and stored at 2 – 80 C to maintain sterility.

5.2 Procedure:

5.2.1 In a conical flask, dissolve 3.0g of TSB powder in 85mls of distilled water.

5.2.2 Add 15mls of glycerol and distribute 1ml volumes of the mixture in Nunc vials arranged in a rack.

5.2.3 Recap the vials loosely and sterilize by autoclaving at 121oC for 15 minutes.

Incorporate autoclave indicators to monitor sterility.

5.2.4 Tighten the caps after sterilization and place the vials to cool on the bench in the media preparation room.

5.2.5 Label the rack (freezing mixture), date of preparation and expiry and then place it in a fridge at 2 – 8o C.

5.2.6 Shelf life of vials is 3 months from date of preparation

6.0 APPENDICES:

None

7.0 REFERENCES:

None

8.0 DOCUMENT CHANGE HISTORY

Version Table:

Version 1.0: Title: Preparation Freezing Mixture	Dated: 21st October 2021	SSP No.: LA08	No. Pages: 4
Version 2.0: Title:	Dated:	SSP No.:	No. Pages:
Version 3.0: Title:	Dated:	SSP No.:	No. Pages:
This document is effective from the date of training/last approval signature and will be reviewed in two years.			

SSP Review and Updating Logs

DATE	NAME OF REVIEWER	SIGNATURE	REASON FOR REVIEW AND CHANGES MADE

SSP AWARENESS LOG

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

Number	Name	Signature	Date (dd/mmm/yyyy)
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