Childhood Acute Illness & Nutrition Network

KEMRI | Wellcome Trust Clinical Trials

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

Study Specific Procedure	**SSP No:** LA06 **Version No:** 1.0 **Supersedes:** None **Effective Date:** 21st October 2021

Title: Sample International Shipment

	NAME	**SIGNATURE**	**DATE**
PREPARER	Robert Musyimi		**30th September 2021**
Q.A. AUTHORITY	Aisha Bwika		**16th October 2021**
APPROVING AUTHORITY	Robert Bandsma		**20th October2021**

1.0 PURPOSE / INTRODUCTION:

The purpose of this SOP is to describe the standard procedures involved in sample shipment from CHAIN PB-SAM site to Kilifi for biorepository and further analysis. This SOP applies inpatients participants who have consented for shipping.

2.0 SCOPE / RESPONSIBILITY

This SOP applies to nursing staff, study clinicians and lab staff of study sites who will be involved in sample shipment. 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. Main CHAIN PB-SAM laboratory coordinator: Caroline Tigoi (email: ctigoi@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 **IATA**: International Air Transport Association
3.4 **DGR:** Dangerous Goods Regulations
3.5 **UN2814:** Code for infectious substances, affecting humans
3.6 **UN2900:** Code for infectious substances, affecting animals
3.7 **UN 3373:** Infectious substances in category B
3.8 **UN 1845**: Code for dry ice, CO_2 and other gases

4.0 MATERIALS

4.1 Approval for shipment from sites' regulatory body
4.2 Customs permit from Kenya
4.3 Approval for import from Kenya
4.4 Excel Box map
4.5 Shipping Styrofoam box with visible UN2814, UN2900, UN1845, UN 3373 and orientation signs
4.6 Bio-hazard shipment bags
4.7 Absorbent tissue
4.8 Dry Ice
4.9 Disposable gloves
4.10 Temperature monitoring devices (Two in every dry ice box)

5.0 METHODOLOGY:

5.1 General considerations

5.1.1 Sample shipment is the most critical procedure in CHAIN PB-SAM study. All processes must be well coordinated with the consigner and consignee been aware of the processes.

5.1.2 Import, export permits and approval from regulatory bodies MUST be available before planning any shipment.

5.1.3 Sites must contact reputable organization for shipment and acquire waybill numbers for tracking purposes, e.g., world courier.

5.1.4 Consigner and consignee must be in communication. The total number of sample aliquot cryoboxes should be communicated during the planning stage. Follow up communication should go on until the samples are received, quality control is done, and feedback is given on the sample status upon reception.

5.1.5 Personnel doing shipments should have a valid IATA and DGR certificates. IATA and DGR classifies Class 6.2 infectious substances into two categories, Biological substance, Category A and Biological substances, Category B:Biological Substance, Category A: an infectious substance which in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals. Biological Substance, Category B: An infectious substance which does not meet the criteria for inclusion in Category A. Infectious substances in category B must be assigned to UN 3373.

5.1.6 All sample boxes MUST be of 133 X 133 X 52 mm dimension. Any samples in different box sizes should not be shipped.

5.1.7 Dry ice is considered a hazardous substance because it expands as it sublimates—that is, reverts from solid back to gas. If the expanding gas cannot escape, the container may rupture and release its contents. Therefore, do not store dry ice in tight fitting containers.

5.1.8 IATA requires triple packaging of samples for shipment. In CHAIN PB-SAM , the specimen tube (primary container) will be transported in a Nalgene cryobox (secondary container). The Nalgene cryobox will be stored in a sealed biohazard shipment bag (Triple container).

5.2 Sample packaging

5.2.1 Print all the shipping manifests and box maps indicating samples stored in each box. Perform a spot check quality control on each box to ensure that samples have been stored in the right positions as per the box maps.

5.2.2 Assemble the Styrofoam box.

5.2.3 Layer absorbent tissue at the base of the box. Pour dry ice to 1/16 full and layer it evenly.

5.2.4 Place the activated temperature monitoring device at the bottom of the box.

5.2.5 Pick 2 Nalgene cryoboxes from the freezer and place them inside biohazard shipment bag in presence of absorbent tissue and seal it. Each shipment bag should hold a maximum of 2 boxes.

5.2.6 Place the biohazard shipment bag in the Styrofoam box.

5.2.7 Depending on the number of boxes to be shipped, repeat steps 2.3 to 2.4 and fill the Styrofoam to half full.

5.2.8 Place the second activated temperature monitoring device at the top of the box before covering it with the final layer of dry ice.

5.2.9 Pour dry ices to “bury” the biological shipment bag.

5.2.10 Place the lid and ensure it fits well to position.

5.2.11 Place excel tray map print out on top of the lid and close the cardboard box.

5.2.12 Seal the Styrofoam cardboard box and attached a shipping address print out as stipulated in 3.3.4 below

5.3 Samples on Transit

5.3.1 Dry ice must be topped up after every 24 hours during transit by the courier company.

5.3.2 Courier company to provide regular updates on the shipment status.

5.3.3 Verify the status of samples upon receipt i.e. number of boxes received and the level of dry ice to ensure samples were frozen during transit.

5.3.4 Download data from the data loggers and share for verification.

FROM

Name of Shipper:

Site of origin:

Name of Facility and Box number:

Tel number:

Cell Number:

Email Address:

TO:

Name of consignee: Moses Mosobo/Robert Musyimi

Name of Facility and Box number: KEMRI-WTRL CGMR-Coast,

P. O box 230, Kilifi, 80108, Kenya

Tel number: +2544041-7522063 or +2544041-7522535

Cell number: +254733816289 or +254725245533 or +254721454459

Email: rmusyimi@kemri-wellcome.org, mmosobo@kemri-wellcome.org,

6.0 APPENDICES:

None

7.0 REFERENCES:

7.1 IATA Packing Instruction 650 – Biological Substances, Category B (http://www.iata.org/NR/rdonlyres/9C7E382B-2536-47CE-84B4-9A883ECFA040/0/Guidance_Doc62DGR_50.pdf)

7.2 DOT 49 CFR Parts 171-180 (http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title49/49cfrv2_02.tpl)

8.0 DOCUMENT CHANGE HISTORY

Version Table:

Version 1.0: Title: **Sample International Shipment Procedure**	Dated: **21st October 2021**	SSP No.: **LA06**	No. Pages: **7**
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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