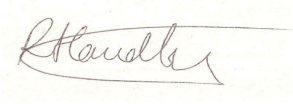
FIEBRE Standard Operating Procedure			
Title	**FIEBRE-15g.01: Receiving and storing FIEBRE samples at LSHTM**		
SOP Reference		***Version***	***Date of effect***
F-15g		1.1.1	23rd Oct 2019

	Name	**Title**	**Signature**	**Date**
Author	Rebecca Handley	LSHTM Laboratory Co-ordinator		2019-10-05
Reviewer	Chrissy h Roberts	LSHTM Laboratory and Data Lead		2019-10-14
Approver				

Revision History

Version No.	**Effective date**	**Reason for change**

SOP User Confirmation

I acknowledge that I have read, understood and agree to follow this SOP

#	**Name (print)**	**Signature**	**Date**
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1. **Title: Receiving and storing FIEBRE samples at LSHTM**
2. **Purpose:** To describe the procedures for receiving and storing FIEBRE samples at LSHTM.
3. **Responsible staff:** Victoria Gould (x2346), Chrissy h Roberts (x2913), Tegwen Marlais (x2866).
4. **Background & Rationale:** The first primary objective of FIEBRE study is to determine the treatable and/or preventable causes of fever in our study population. Multiple causative agents of fever are therefore being investigated. Some laboratory testing is being done on site, but serology and other laboratory tests are being completed at internationally recognized reference laboratories. Samples from study sites that are for testing at international reference laboratories will first be shipped to the London School of Hygiene and Tropical Medicine (LSHTM) and transferred from there. These specimens have been collected primarily from sick people and are therefore likely to contain pathogens both known and unknown, all samples will therefore be handled and stored within the CL3 laboratories facility and treated as if they contain HG3 pathogens. This SOP explains the procedures for receiving, unpacking and storing these samples within the CL3 laboratories (425a) at LSHTM.

5. **Supplies and Material**

5.1 2 pairs of cryogloves

5.2 – 70 °C freezer

5.3 Safety box cutter

5.4 Laptop with FluidX intellicode software and FluidX Impression™ barcode scanner

5.1 Samples, those shipped on dry ice will be stored within cryoboxes in individual Ziploc bags, four boxes within one 650 bio-pouch within an outer tertiary container.

5.2 Nitrile gloves, back fastening lab coat, disposable over-sleeves

5.3 Disinfectants: 70 % ethanol and Biocleanse (made fresh daily)

5.4 Autoclave bins

5.5 Blue roll

6. Procedures

6.1 All work within the CL3, including unloading shipments will occur during normal office hours (Monday-Friday, 9-5pm).

6.2 Two people are required to unload each shipment. Person A will be responsible for opening tertiary containers and performing the initial visual inspection. Person A should wear a white lab coat and cyogloves. Person B will be responsible for loading samples into the freezer and will wear a back-fastening lab coat, nitrile gloves and cyrogloves.

6.3 Once notified of the shipment's arrival at LSHTM, all boxes should be transported to the CL3 suite and held in the corridor.

6.4 The door between 425a and the lobby 425b will be propped open whilst boxes are being unloaded. If the process is interrupted e.g. for a break the doors will be shut and locked.

6.5 Boxes should be moved one at a time into room KS425b (lobby). Person A will be responsible for opening the outer boxes and will remain in the lobby. Person A will carefully open each box using the safety box cutter. With the lid removed, Person A will visually inspect each 650 bio-pouch for signs of damage or leakage to its contents during shipping (see 7.1)

6.6 Cryoboxes within 650 bio-pouches should be handed to a second person (person B) situated within the lab (425a). Person B will transfer each bio-pouch (containing four cryoboxes) to the Class I microbiological safety cabinet (MSC). Person B will then remove these cryoboxes from the 650-bio-pouch and re-inspected for signs of leakage. If box and samples are intact, then the individual within Ziploc bags will be moved into the -70 °C freezer.

6.7 The location of the box within the freezer will be recorded within the biobanking system or excel spreadsheet. Cryogloves will be worn when handling dry ice or frozen samples.

6.8 Once the entire tertiary box has been emptied of bio-pouches, it will be returned to the CL3 suite corridor. The lid should be left off the box to allow the dry ice to evaporate. This procedure should be followed for every tertiary container.

6.9 As soon as the dry ice has fully evaporated the tertiary boxes can be removed from the CL3 suite and stored in a suitable location.

6.10 Notify RIGO of all HTA relevant samples now stored. HTA relevant samples collected during the FIEBRE study include:

- Buffy Coat
- Whole blood

- Red Cell Pellet

7. In the event of a spill or breakage

7.1 If there is any sign of leakage unpacking the outer box in the lobby, then person A should immediately push the box and its contents into 425a. Person B should immediately remove their lab coat and leave the laboratory. Contact the safety office to determine next steps.

7.2 Sign of spills or breakage seen when removing cryoboxes from bio-pouches within the in the MSC:

7.2.1 If the bio-pouch has been opened: remove the unaffected cryoboxes from the bio-pouch, spray down with ethanol and transfer to the freezer. Do not remove the damaged box/boxes from their Ziploc bags. Place the damaged box/boxes (within their Ziploc bags) into new Ziploc bag(s), spay down with ethanol and transfer to the freezer. When entering freezer location details into the excel spreadsheet/bio-banking software make sure there is a clear note that there may be a leak/spill which can be carefully examined and disinfected at a later date.

7.2.2 If the bio-pouch remains sealed when the spill or leak is noticed, spray down with ethanol and transfer the bio-pouch and its contents to the freezer. Make a note in the excel or biobanking software (as above).

7.3 Safety office contact details:

7.3.1 Call: 020 7299 4615 or 07808 905958