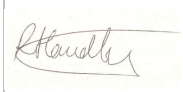
FIEBRE Standard Operating Procedure F.15b	
Title	**Sample storage at sites and selection and preparation for shipping participant samples (whole blood, plasma, serum, blood cell pellet, buffy coat, PAXgene tubes and NP/OP swabs)**

SOP Reference	*Version*	*Date of effect*
F.15b	1.1.1	01 Apr 2019

SOP Development

	Name	Title	Signature	Date
Author	Rebecca Handley	LSHTM Laboratory Co-ordinator		01/10/2019
Reviewer	Chrissy h Roberts	LSHTM FIEBRE laboratory expert		14/10/2019
Approver	Heidi Hopkins	FIEBRE scientific program coordinator		18 Nov 2019

Review Tracker

Due date for next review	Reviewer name	Signature	Date reviewed

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: SAMPLE STORAGE AT SITES AND SELECTION AND PREPARATION FOR SHIPPING**
2. **Purpose:** To describe the procedures for participant samples selection and shipment from study sites to LSHTM. This SOP describes procedures for selection, packing, and shipping of whole blood, plasma, serum, blood cell pellet, buffy coat, PAXgene tubes and naso-/oropharyngeal swab specimens.
3. **Responsible staff:** FIEBRE laboratory and co-ordination staff [site-specific]
4. **Background & Rationale:** The first primary objective of the FIEBRE study is to determine the treatable and/or preventable causes of fever in our study population. Many infectious agents that may cause fever are therefore being sought with laboratory testing; some laboratory testing is being done on site, while serology and other laboratory tests are being completed at internationally recognised reference laboratories. It is therefore very important that all samples are stored, packed, and shipped correctly. Samples will first be shipped from each study site to the London School of Hygiene and Tropical Medicine (LSHTM). Then laboratory staff at LSHTM will transfer aliquots to each reference laboratory. This SOP explains shipping requirements for transfer of samples from each site to LSHTM.
5. **Supplies and Materials**
    - Sample logbook (paper and ODK)
    - 0.5 mL and 2 mL cryovials containing participant samples
    - Cryoboxes
    - Gloves (single-use latex or vinyl)
    - Cryogloves for handling dry ice
    - Biohazard disposal system

- Lab surface disinfectant (e.g. Virkon)
- Packaging, shipping labels and dry ice (to be provided by courier)

6. Procedures:

6.1 Storage of samples at the study site

6.11 The table below specifies the container and temperature for storage of each sample type.

Sample type	Storage container	Storage temperature	Where to find more information
Serum	2 mL cryovials	-80°C	SOP F-05
Plasma	2 mL cryovials	-80°C	SOP F-05
Red blood cell pellet	2 mL cryovials	-80°C	SOP F-05
Whole blood	2 mL cryovials	-80°C	SOP F-05
Buffy coat	0.5 mL cryovials	-80°C	SOP F-05
PAXgene tubes	PAXgene tubes	-20°C for 24 hours then -80°C	SOP F-19
Pharyngeal (NP and OP*) swabs	Dry sterile tube, 2-10 mL	-80°C	SOP F-05
Giemsa-stained microscopy slides	Microscopy slide boxes	Room temperature	SOP F-07a

* NP and OP = naso- and oropharyngeal

6.2 Preparation for shipment

6.2.1 This SOP covers the selection and shipping of the following samples:

Whole blood, serum, plasma, red cell pellet, buffy coat, pharyngeal swabs and microscopy slides.

6.2.2 Dried blood spots (see SOP F.15a) will be shipped to LSHTM at ambient temperature and will be described in a different SOP.

6.2.3 Bacterial and mycobacterial isolates will be shipped separately and sent directly from each study site to reference laboratories (see SOP-F-15c).

6.3 Selecting Samples for Shipment

6.3.1 Identify the samples to be shipped, in discussion with your study site co-ordinator/s and LSHTM team.

6.3.2 Samples collected from participants at day 0 must be stored at the study site for a minimum of 2 (two) months before shipping. Therefore, prepare for shipment only samples collected at least 2 months prior to the shipment date.

6.3.3 If applicable (site specific) complete a proforma/shipping list of the exact number of samples to be shipped. (Please note: samples cannot be added to a list at a later date, because the original proforma will be used to apply for customs permit).

6.3.4 Contact an appropriate team member at your study site, and/or Becca Handley [Rebecca.handley1@lshtm.ac.uk], to obtain a price quote for the samples included on the proforma. The number of cryoboxes and estimated weight of the shipment will be needed to obtain an accurate quote.

6.3.5 Once you have received a price quote, confirm shipment dates with LSHTM team.

6.3.6 Prepare an Excel spreadsheet with the following information for each sample to be shipped: participant ID, sample ID, and sample type. Email the spreadsheet and box-maps of the samples to Becca Handley [rebecca.handley1@lshtm.ac.uk] once the shipment has been confirmed.

7 Packaging and labelling of Category B samples for shipment

7.1 Shipping classification

7.1.1 Whole blood, serum, plasma, red cell pellet, buffy coat, pharyngeal swabs, PAXgene tubes and Giemsa-stained microscopy slides will be shipped as UN3373 Category B biological substances. Category B includes infectious substances that are in a form not generally capable of causing permanent disability, life-threatening or fatal disease to humans or animals when exposure to them occurs.

7.1.2 All samples stored at -80°C must be shipped on dry ice. Dry ice will be provided by the courier.

7.2 **Packaging of dry ice samples–** all Category B shipments must be triple packaged in accordance with International Air Transport Association (IATA) guidelines

7.2.1 The primary receptacle is the 0.5 mL or 2 mL leak-proof cryotube holding each sample. These should be securely sealed. Package and ship the cryotubes within the plastic cryoboxes where they are currently stored. As an extra precaution all FIEBRE cryoboxes will be shipped within an additional Ziploc bag, pack this with a suitable absorbent material, such as blue roll, (such as blue roll) to absorb any spills that may occur during transport (Figure 1 A and B).

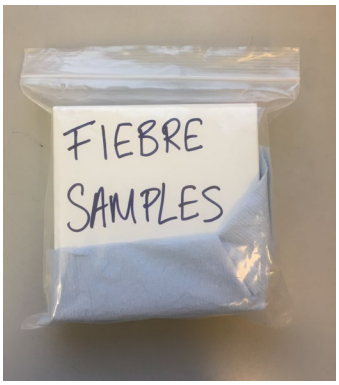
Figure 1: Example of how cryoboxes should be packed for shipping.

A

Place cryoboxes in a Ziploc bag with enough blue roll to absorb all the contents in case of a spill

Cryobox and absorbent material within a Ziploc bag

B



C

Place a maximum of 4 cryoboxes in 1 Bio-pouch (the “secondary container”). The bio-pouches will be provided by the courier.

7.2.2 The secondary container is a leak-proof 650- bio-pouch bag, The courier will supply these bags. Pack a maximum of 4 cryoboxes (within their individual Ziploc bags) into one bio-pouch (figure 1 C).

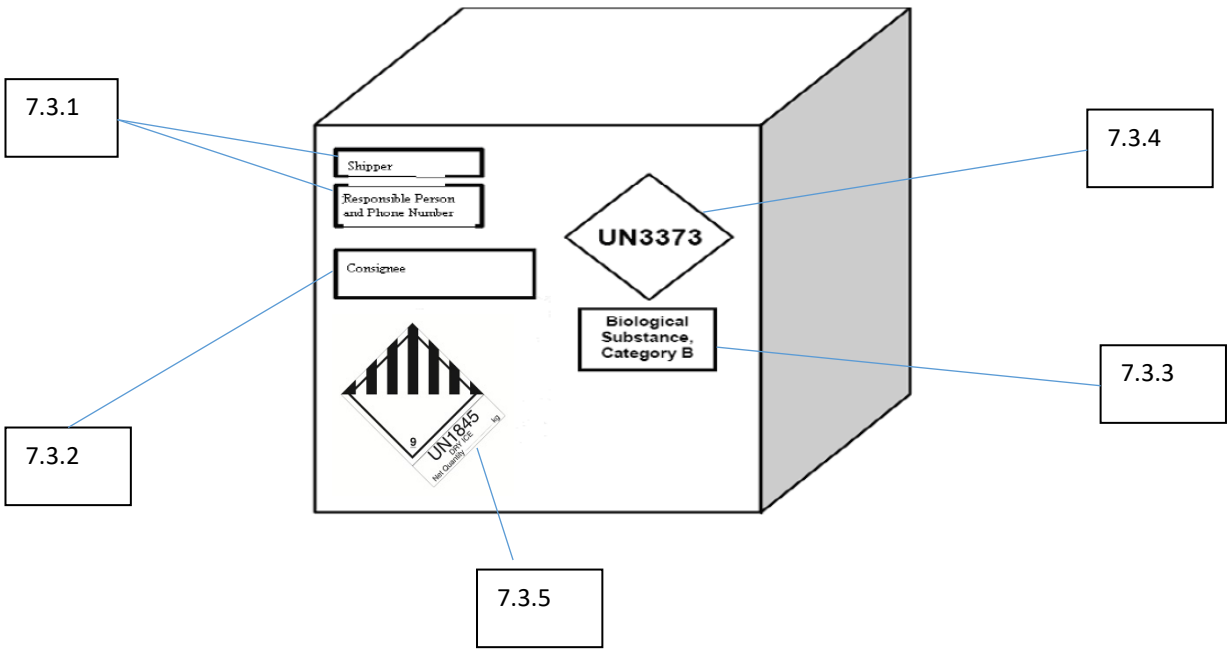
7.2.3 The third layer is a rigid outer box, which will hold the dry ice container. The courier will provide these boxes and the dry ice. These boxes should come marked with the appropriate hazard labels (see 7.4).

7.3 Packaging of microscopy slides

7.3.1 Microscopy slides will also be shipped under UN3373
7.3.2 The primary container will be a secure microscope slide box
7.3.3 The secondary container will be a 650 bio-pouch (these will be provided by the courier)
7.3.4 The third container will be an outer box complete with the correct labelling for Category B shipments (see 7.4). Ensure there is lots of suitable cushioning material surrounding the slide boxes to prevent movement during shipping.

7.4 Labelling for Category B outer boxes

7.4.1 Sender's name and address (your own contact information).
7.4.2 Recipient's name and address (see 7.4).
7.4.3 The words ”Biological Substance, Category B”.
7.4.4 UN3373 label (supplied by the courier)
7.4.5 If the package contains dry ice: A class 9 label is needed along with the words “UN1845 Dry ice” and the weight of dry ice in kilograms
7.4.6 Label each box consecutively, i.e. “Box 1 of 10”, “Box 2 of 10”, “Box 3 of 10”, and so on.



7.5 Recipient address:

Rebecca Handley, Office 266
London School of Hygiene and Tropical Medicine
Goods In, Malet Street (Keppel St. Building)
London
WC1E 7HT
United Kingdom
Telephone: +44 207 927 8866

8 Documentation required for shipping

8.1 Place one copy of each of the following documents in a transparent envelope and affix to the outer box.

a. Completed MTA (material transfer agreement) signed by both parties (LSHTM and your study site)
b. A customs invoice written on site-specific headed paper. This should include the number and volume of each sample type shipped. Use a nominal commercial value of £10 GBP (ten Great British pounds sterling). Contact Becca Handley [Rebecca.handley1@lshtm.ac.uk] for a template if needed.
c. A certificate of donation on site-specific headed paper. Contact Becca Handley [Rebecca.handley1@lshtm.ac.uk] for a template if needed.

8.2 Place a second copy of each document within the outer package.

9 On the day of shipping

9.1 Ensure each cryovial is intact with no leak before transport. Check each cryobox for signs of breakage.

9.2 If not already done, pack each cryobox inside a single Ziploc bag with the absorbent material

9.3 Pack up to four cryoboxes within one 650- biohazard bag. (These biohazard bags will be provided by the courier)

9.4 The courier will provide dry ice, and outer containers large enough to fit a maximum of 8 (eight) cryoboxes. Remove dry ice from each outer box to allow space for a maximum of 8 (eight) cryoboxes per outer box. Use cryogloves or a scoop when handling the dry-ice. Do not touch dry-ice with latex or vinyl lab gloves or bare hands.

9.5 Pack the cryoboxes and dry ice into the outer box so that the cryoboxes are completely surrounded by dry ice. Fill each outer box to capacity with dry ice.

9.6 Ensure that the courier has attached the correct hazard labels to each of the outer package (see section 7.3)

10 Documentation:

- FIEBRE protocol (version 3.0, 31 Oct 2018) section 7.3.2
- Sample log book (ODK or paper)
- SOPs F-05, F-08a, F-08b, F-08c, F-07a and F19 for more information of storage of specific samples