

FIEBRE Standard Operating Procedure F.19		
Title	Collection and storage of PAXgene tube	
<i>SOP Reference</i>	<i>Version</i>	<i>Date of effect</i>
F.19	1.1.2	05 Feb 2019

SOP Development

	Name	Title	Signature	Date
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Review Tracker

Due date for next review	Reviewer name	Signature	Date reviewed
27 Feb 2019	Kate Haigh		05 Feb 19
05 May 2019			

Revision History

Version No.	Effective date	Reason for change
1.1.2	05 Feb 2019	Added detail in background

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: COLLECTION AND STORAGE OF PAXGENE TUBE

2 Purpose: To describe the procedures for collecting blood in a PAXgene tube and storage for later RNA extraction.

3 Responsible staff: FIEBRE clinical and laboratory staff [**adjust based on site personnel**]

4 Background & Rationale: Broadly speaking, cells “transcribe” their DNA into RNA, and then “translate” the RNA into proteins that perform cell functions or activities for example to fight infections. Different types of infection can result in different unique patterns of RNA “transcriptomes”. For the FIEBRE study, we are studying these unique patterns to see if we can develop better diagnostic tests to identify infections.

We will obtain blood for RNA study from FIEBRE participants aged ≥ 15 years [**once ethics approval has been obtained at the site**]. Special storage tubes called PAXgene tubes are required to stabilise or preserve the RNA for laboratory analysis. PAXgene tubes should be collected on all patients aged ≥ 15 years (maximum 180 participants) all adult controls (maximum 20 participants) at each site.

PAXgene samples will be stored and shipped to a central laboratory at LSHTM for testing.

This SOP describes the procedures for obtaining, processing and storing blood samples in PAXgene tubes.

5 Supplies and Materials

- Sample logbook (paper or Open Data Kit [ODK])
- Sample labels with patient’s QR code
- PAXgene blood RNA tube
- Tube rack
- Blood drawing (phlebotomy) equipment as in SOP F-04

6 Procedures:

6.1 Checking participant eligibility for PAXgene tube sampling

6.1.1 Check patient age to ensure they are ≥ 15 years

6.1.2 Check the number of PAXgene samples that have been collected at your site. The target is 180 adult patients and 20 controls. If this number has been reached then check with site PI before collecting any further samples for PAXgene

6.2 Collecting venous blood into a PAXgene tube

All blood samples must be considered potentially infectious. Study staff must use universal precautions in obtaining and handling blood samples.

6.2.1 Collect blood as described in SOP F-04

6.2.2 Draw 28.5ml of blood in African sites and 23.5ml of blood in Lao; follow the order of collection as per SOP F-04, using the last 2.5ml for the PAXgene tube. Use the same single needle insertion and blood collection tubing as for the other samples

6.2.3 Fill the bottles in the order indicated in SOP F-04. The PAXgene tube is the last tube to be filled. Take care so that the tube contents do not syphon back up the tube into the patient's vein

6.2.4 Gently tilt (invert) the PAXgene tube back and forth 10 times and place it in the [rack/cooler box.]

6.2.5 **Apply sample label with the patient's QR code to the tube**

6.3 Storing blood samples in PAXgene tubes

6.3.1 Ensure each PAXgene tube is labelled correctly

6.3.2 Store each PAXgene tube in a cryobox designated only for PAXgene tubes

6.3.3 **IMPORTANT NOTE:** Freeze PAXgene tubes at -20°C for at least 24 hours. After 24 hours, transfer them into the -80°C for storage. (This minimises the risk of the tubes cracking when thawed)

7 Documentation: FIEBRE protocol (version 3.0, 31 Oct 2018) section 7.3.2, 7.4.2, 7.5.3 and 7.6.7 and Sample Log Book [ODK vs paper]