FIEBRE Standard Operating Procedure F.14			
Title	**Collection and Processing of Samples from Controls: Venous Blood, Pharyngeal Swabs**		
SOP Reference		***Version***	***Date of effect***
F.14		2.2.1	27 Dec 2018

SOP Development

	Name	Title	Signature	Date
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Review Tracker

Due date for next review	Reviewer name	Signature	Date reviewed
30 June 2018	Kate Haigh		22 Nov 18
20 Dec 2018	Kate Haigh		27 Dec 18
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Revision History

Version No.	Effective date	Reason for change
2.0	22 Nov 2018	Updated content to include collection and processing of samples
2.2.1	27 Dec 2018	To include requirement for buffy coat from control samples

SOP User Confirmation

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

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1 Title: COLLECTION AND PROCESSING OF SAMPLES FROM CONTROLS: VENOUS BLOOD, PHARYNGEAL SWABS

2 Purpose:

To describe the procedures for collecting and processing venous blood and pharyngeal swabs from community control participants in the FIEBRE study.

3 Responsible staff:

[adjust based on site personnel]

4 Background & Rationale:

Interpreting the results of some serological tests and pharyngeal swab assays requires knowledge of background prevalence of infection or colonization in the study population. Samples from FIEBRE community control participants will be used for this purpose.

Collection and processing of samples from FIEBRE controls is very similar to the procedures described for patients on Day 0 in SOPs F.04 and F.05, and on Day 28 in SOP F.11. The key differences are in the type and volume of samples. This SOP describes the type and volume of samples to be obtained and processed from control participants.

5 Supplies and Materials

- Sample logbook (paper or ODK)
- Sample labels with participant's QR code
- Gloves (single-use latex or vinyl)
- Sharps bin
- Butterfly cannula system with connecting tube, or hypodermic needle with syringe (check gauge size)
- Phlebotomy (blood letting) system adaptor (security device)
- Alcohol swabs (or other topical skin disinfectant)
- Optional: EMLA cream
- Tourniquet
- Cotton wool, plaster, or gauze with paper tape
- EDTA tube (check volume in tables below)
- Serum tube/s (check volume in tables below)
- Two pharyngeal swabs (plastic handle)
- 10 mL plain Vacutainer or screw-top tube (for pharyngeal swabs)
- Tube rack
- Cooler box or other carrying container

6 Procedures:

6.1 Collecting venous blood

Blood will be collected for testing at the study site, for testing at international reference laboratories, and for future research use. Control participants will have an EDTA sample taken to prepare point-of-care tests, buffy coat and filter paper spots, and to prepare plasma for storage and future research use. The plain tube is used to prepare serum, which will be stored and shipped to international reference labs for diagnostic testing, and for future research use.

For procedures on how to collect venous blood samples, see SOP F-04. The volume of blood taken from each control will be either 5ml or 10ml, which is [site-specific] depending on ethical approval. Please see the table at the end of this SOP for guidance on blood volumes.

6.2 Collecting pharyngeal (NP and OP swabs)

Naso- and oropharyngeal (NP and OP) swab samples will be collected to test for respiratory viruses at an international reference laboratory.

[Note: Both oropharyngeal (OP) and NP swabs may only be obtained once ethics approval is in place; check with your study co-ordinator. If both OP and NP swabs are obtained for a study participant, both swabs should be received, stored and shipped together in one tube.]

For the procedure of how to collect pharyngeal swabs, see SOP F-04.

6.3 Processing EDTA, plain tube and pharyngeal swabs

For details on processing EDTA and plain tubes and pharyngeal swabs, please see SOP F-05.

7 Documentation: FIEBRE protocol (version 2.7, 15 Oct 2018) section 7.3.2 and 7.5.3;

see also:

SOP F-04 Collection of patient samples on Day 0

SOP F-05 Processing of patient sampes on Day 0

NOTE: If your site has ethics approval to draw 10 mL blood for patients with body weight >7 kg and age ≥5 years and <15 years, use Table A.

If your site has approval for only 5 mL for this group, use Table B. See protocol section 7.5.3 for details.

SOP F-14 TABLE A: Blood sampling volumes and sequence for CONTROLS (version 2.0, 20 Aug 2018)

Filling sequence	ADULTS (≥15 years)	CHILDREN (≥5 to <15 years, body weight >7 kg)	CHILDREN (<5 years, body weight ≥2 kg)
1	**Plain tube – 9 mL blood** Centrifuge → 4-5 mL of serum (Discard clot)	**Plain tube – 9 mL blood** Centrifuge → 4-5 mL of serum (Discard clot)	**Plain tube – 4 mL blood** Centrifuge → 2-2.5 mL of serum (Discard clot)
2	**EDTA tube – 1 mL blood** <200 uL whole blood for POCTs and filter paper spots (30 uL malaria microscopy, 20 uL malaria RDT, 6 x 10 uL filter paper spots, 50 uL HIV RDT at African sites) >800 uL centrifuged → plasma for biomarkers, [buffy coat], cell pellet		
3	PAXgene for RNA* (subset 20 controls) **2.5 mL blood**	NONE	NONE
Actual minimum blood draw	10 mL (12.5 mL with PAXgene)*	10 mL	5 mL
Maximum blood draw allowed	10 mL (12.5 mL with PAXgene)*	10 mL	5 mL

* PAXgene sample to be obtained only in randomly selected subset of 20 adult controls per study site; ensure local ethics approval.

NOTE: If your site has ethics approval to draw 10 mL blood for patients with body weight >7 kg and age ≥5 years and <15 years, use Table A.

If your site has approval for only 5 mL for this group, use Table B. See protocol section 7.5.3 for details.

SOP F-14 TABLE B: Blood sampling volumes and sequence for CONTROLS (version 2.0, 20 Aug 2018)

Filling sequence	ADULTS (≥15 years)	CHILDREN (<15 years of any body weight ≥ 2 kg)
1	**Plain tube – 9 mL blood** Centrifuge → 4-5 mL of serum (Discard clot)	**Plain tube – 4 mL blood** Centrifuge → 2-2.5 mL of serum (Discard clot)
2	**EDTA tube – 1 mL blood** <200 uL whole blood for POCTs and filter paper spots (30 uL malaria microscopy, 20 uL malaria RDT, 6 x 10 uL filter paper spots, 50 uL HIV RDT at African sites) >800 uL centrifuged → plasma for biomarkers, [buffy coat], cell pellet	
3	PAXgene for RNA* (subset 20 controls) **2.5 mL blood**	NONE
Actual minimum blood draw	10 mL (12.5 mL with PAXgene)*	5 mL
Maximum blood draw allowed	10 mL (12.5 mL with PAXgene)*	5 mL

* PAXgene sample to be obtained only in randomly selected subset of 20 adult controls per study site; ensure local ethics approval.