

FIEBRE Standard Operating Procedure F.07c

Title	Selection of prepared slides for external quality control		
SOP Reference	Version	Date of effect	
F.07c	1.1.1	10 Mar 2019	

SOP Development

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Due date for next review	Reviewer name	Signature	Date reviewed
20 Apr 2019			

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

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1 Title: SELECTION OF PREPARED SLIDES FOR EXTERNAL QUALITY CONTROL

2 Purpose: To describe the procedures for selection of slides (prepared as per SOP F-07a and in some sites read for *Plasmodium* species as per SOP F-07b) for external quality control.

3 Responsible staff: FIEBRE laboratory staff

4 Background & Rationale: For study purposes, for all participants (patients and controls) at the time of enrolment a thick and thin blood smear will be prepared, fixed and stained with Giemsa (see SOP F-07a).

If blood smear microscopy is routinely performed for clinical care at a FIEBRE study site, for all study patients a blood smear will be prepared and read according to local standards for this purpose (see SOP F-07b for malaria blood smear microscopy). This smear will be stored according to F-07a. Not all FIEBRE sites have expert microscopists (according to WHO research standards) on site.

At sites with expert microscopists, there will be internal quality control carried out. External quality control is required for all sites to ensure reproducibility and validity of results. External quality control will be completed by the Parasitology laboratory at the Liverpool School of Tropical Medicine.

5 Supplies and Materials

- Sample logbook [paper or ODK]
- Participants' prepared thick and thin blood smear slide/s labelled with QR codes
- Malaria microscopy logbook [paper or ODK]
- Gloves (single-use latex or vinyl)
- Biohazard disposal system

6 Procedures:

Initial reads of slides will be completed by expert microscopists on site where available or otherwise following discussion with the Scientific Program Co-ordinator.

6.1 Selection of slides for external quality control for malaria

- 6.1.1 A random 10% sample of *Plasmodium* species microscopy-positive and 10% of microscopy-negative slides must be sent to the external quality assurance laboratory (see SOP F-15 for storage and shipping)
- 6.1.2 These random 10% of slides for external quality control will be selected centrally by the data team/s using appropriate algorithms and will be communicated to each study site
- 6.1.3 If results at the quality assurance laboratory are discordant from a site's results (positive/negative, parasite species or density) beyond a certain threshold, more slides from the affected site will be sent to the Liverpool School of Tropical Medicine

6.2 Selection of slides for external quality control for *Borrelia* spp and other pathogens detectable by microscopy

- 6.2.1 A random 10% sample of all slides not overlapping with those sent for malaria quality control as per 6.1 will be sent to the external quality assurance laboratory for review
- 6.2.2 These random 10% of slides for external quality control will be selected centrally by the data team/s using appropriate algorithms and will be communicated to each study site
- 6.2.3 If a proportion is positive over a certain threshold (to be decided by external lab and co-investigators), further smears will be read from that site

7 Documentation: FIEBRE protocol (version 3.0, 31 Oct 2018) section 7.6, and SOPs F-07a, F-07b and F-15