

FIEBRE Standard Operating Procedure F.07b

Title	Malaria blood smear microscopy: slide reading, recording and internal quality control		
SOP Reference	Version	Date of effect	
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SOP Development

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Due date for next review	Reviewer name	Signature	Date reviewed
20 Apr 19			

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: MALARIA MICROSCOPY: SLIDE READING, RECORDING AND INTERNAL QUALITY CONTROL

2 Purpose: To describe the procedures for performing malaria microscopy on Giemsa-stained thick and thin blood smears for participants in the FIEBRE study and internal quality control of microscopy results.

Please note this SOP is only of relevance at sites where there are expert microscopists on site according to WHO research standards. At other sites, the slides should be stained and stored as per SOP F-07a and shipped as per SOPs F-07c and F-15.

3 Responsible staff: FIEBRE laboratory staff [site-specific]

4 Background & Rationale: 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. All study participants who test positive for malaria, by local microscopy or malaria RDT (see SOP F-06a), should receive appropriate antimalarial treatment according to national malaria guidelines.

In addition, 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). Smears from mRDT-positive participants will be read by expert microscopists at site where expertise allows for presence or absence, density and species of *Plasmodium*. 10% of randomly selected mRDT negative smears will also be read on site. For **internal quality control**, smears will be read independently by two expert microscopists, with discordant results resolved by a third expert reader. Where the site does not have expert microscopy on site, slides to be stained with Giemsa as per SOP F-07a and selected for shipping as per SOPs F-07c and F-15.

In addition, a 10% sample of *Plasmodium* microscopy positive and 10% sample of *Plasmodium* microscopy negative smears from each site will be shipped to the Liverpool School of Tropical Medicine (Liverpool, United Kingdom) for quality assurance according to WHO malaria microscopy standards.

The random 10% of slides in each category will be centrally selected by the data team/s according to algorithm and will be communicated to each site.

5 Supplies and Materials

- Sample logbook [paper or ODK]
- Malaria microscopy logbook [paper or ODK]
- Participant's thick and thin blood smears prepared as per SOP F-07a
- Gloves (single-use latex or vinyl)
- Biohazard disposal system

6 Procedures:

6.1 Reading thick and thin smears according to WHO standard protocols

[Please note that this is site-specific, for those sites where there is not expert microscopists available, this will not be done on site]

6.1.1 Microscopy is done on blinded slides in FIEBRE study as the microscopist will not be aware of patient details e.g. MRDT result

6.1.2 Slide quality will be assessed as per WHO guidelines by microscopist

6.1.3 Parasite recognition and parasite density estimation will be documented by microscopist [documentation may be site-specific, please add your site's process here]

6.1.4 Where microscopy is completed on site, results of any parasite positive samples will be communicated to study team

6.1.5 Microscopy-positive and microscopy-negative slides should be stored in separate slide boxes to ensure ease of finding slides when selected for external quality control (see below)

6.2 Internal quality control of malaria blood smear microscopy

6.2.1 Smears should be read independently by two expert microscopists (according to WHO research standards)

6.2.2 Any discordance in results should be resolved by a third expert reader

6.3 External quality control of malaria blood smear microscopy

6.3.1 See SOP F-07c for details of external quality control of all blood smears

7 Documentation: FIEBRE protocol (version 3.0, 31 Oct 2018) section 7.6, [WHO standard manuals for malaria microscopy and quality control in research settings and WHO MM-SOP-04 and MM-SOP-07A], SOPs F-07a and F-07c