

<b>FIEBRE Standard Operating Procedure F.06a</b>		
<b>Title</b>	<b>Malaria RDT Preparation, Reading and Results Recording</b>	
<i>SOP Reference</i>	<i>Version</i>	<i>Date of effect</i>
F.06a	2.1.2	18 Dec 2018

### SOP Development

	<b>Name</b>	<b>Title</b>	<b>Signature</b>	<b>Date</b>
<b>Author</b>	Heidi Hopkins	Scientific Program Coord.		
<b>Reviewer</b>	Kate Haigh	Clinical Governance Coord.		
<b>Approver</b>				

### Review Tracker

<b>Due date for next review</b>	<b>Reviewer name</b>	<b>Signature</b>	<b>Date reviewed</b>
30 June 2018	Kate Haigh		30 Nov 18
18 Dec 2018	Kate Haigh		18 Nov 18
12 Feb 2018			

### Revision History

<b>Version No.</b>	<b>Effective date</b>	<b>Reason for change</b>
2.0	20 Nov 2018	Updated to reflect that there is no longer a requirement to photograph the MRDTs
2.1.2	18 Dec 2018	Minor formatting corrections

## SOP User Confirmation

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

#	Name (print)	Signature	Date
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

## **1 Title: MALARIA RAPID DIAGNOSTIC TEST (mRDT) PREPARATION, READING AND RESULTS RECORDING**

**2 Purpose:** To describe the procedures for preparing, reading, and recording results of malaria rapid diagnostic tests (mRDTs) for participants in the FIEBRE study.

**3 Responsible staff:** FIEBRE laboratory staff [[adjust based on site personnel](#)]

**4 Background & Rationale:** For all FIEBRE study patients on Day 0, and for all control participants, a mRDT will be performed. Malaria rapid diagnostic tests (mRDTs) detect malaria parasite antigen (protein) in a person's blood.

For the FIEBRE study, we will use a combination mRDT that detects two different parasite antigens: histidine-rich protein 2 (HRP2) which is produced only by *Plasmodium falciparum* parasites; and pan-specific *Plasmodium* lactate dehydrogenase (pLDH) which is produced by all malaria parasite species.

This SOP may be used in conjunction with the mRDT manufacturer's package insert, and/or WHO job aids (pictorial instruction sheets).

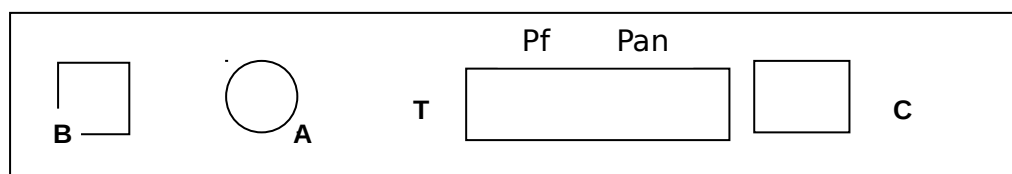
## **5 Supplies and Materials**

- Sample logbook (paper or ODK)
- Malaria mRDT [results form](#) (paper or ODK)
- HRP2/pLDH malaria mRDT in individual sealed pouch
- Malaria mRDT buffer (provided in test kit)
- Participant's whole blood sample in EDTA tube
- Sample labels with patient's QR code
- Gloves (single-use latex or vinyl)
- Tube rack
- Calibrated pipette and pipette tips, or blood transfer device provided in mRDT kit
- Sharps bin
- Biohazard disposal system

## 6 Procedures:

### 6.1 Preparing the malaria mRDT

- 6.1.1 Wear latex or vinyl gloves. Open one test pouch, and remove the mRDT, blood transfer device, and desiccant. [Use the mRDT immediately after opening the pouch; do not use an mRDT that was opened more than one hour ago.](#)
- 6.1.2 Check the colour of the desiccant – it should be [yellow](#). If it is [green](#), do not use the mRDT. Only use mRDTs from pouches with [yellow](#) desiccant.
- 6.1.3 With the blood transfer device or a calibrated pipette, transfer 5 uL (five microliters) of whole blood from the EDTA tube to the sample well, indicated by 'A' in the diagram here. Carefully place the blood directly onto the pad in the sample well, so that no blood is left on the sides of the well.



- 6.1.4 Use the buffer bottle provided with the mRDT kit to dispense [4 \(four\)](#) drops of buffer into well 'B'.
- 6.1.5 Set the timer for [15 \(fifteen\)](#) minutes. Place the mRDT on a clean, flat surface where it will not be disturbed.
- 6.1.6 When the timer beeps, read the mRDT as described below.

### 6.2 Reading the malaria RDT

- 6.2.1 When the timer beeps, promptly check the mRDT. If there is still blood (red-pink staining) in the background of the test window, re-set the timer for an additional [5 to 10 \(five to ten\)](#) minutes before reading and recording results. Do not wait longer than 30 minutes to read and record a mRDT result.
- 6.2.2 When reading a mRDT, first check for the control line in window 'C'. If no pink-purple band appears in the control window 'C', the test result is invalid. If no band appears in window 'C', repeat the test with another mRDT.

6.2.3 If the control line is present, look next at the test window 'T'. The test window may show one, two, or no pink-purple bands. **Even a faint band should be considered a positive result** – if in doubt, use your best judgment.

- A band at both positions, Pf and Pan, indicates a *P. falciparum* mono- or mixed infection.
- A single band at the Pf position indicates a *P. falciparum* infection.
- A single band at the Pan position indicates a non-falciparum infection (*P. malariae*, *P. ovale*, *P. vivax*, *P. knowlesi*, or a combination of these).
- If there is no visible band in the test window, the test is negative.

### **6.3 Recording the malaria RDT result**

6.3.1 Immediately after reading the mRDT, record the mRDT result – negative, Pf positive only, Pan positive only, or Pf and Pan positive – in the patient's ODK record or paper logbook.

6.3.2 Report any positive result as soon as possible to the clinical team managing the study participant.

**7 Documentation:** FIEBRE protocol (version 1.0, 01 Oct 2017) section 7.6.1;

see also package insert for SD Bioline Malaria Ag P.f/Pan (05FK60) malaria RDT,

and WHO training materials at

<http://www.who.int/malaria/areas/diagnosis/rapid-diagnostic-tests/job-aids/en/>