WHO Prequalification of In Vitro Diagnostics Programme
PUBLIC REPORT

Product: ParaHIT f Ver. 1.0 Rapid Test for P.falciparum Malaria Device

WHO Reference Number: PQDx 0062-023-00

ParaHITf Ver. 1.0 Rapid Test for P.falciparum Malaria Device with product codes **55IC104-10, 55IC104-25, 55IC104-50, 55IC116-10, 55IC116-25, and 55IC116-50** manufactured by Arkray Healthcare Private Limited., **CE-marked regulatory version**, was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 7 October 2014.

Summary of prequalification status for ParaHITf Ver. 1.0 Rapid Test for P. falciparum Malaria Device

	Date	Outcome
Prequalification listing	7 October 2014	listed
Dossier assessment	28 March 2014	MR
Site inspection(s) of quality management system	18 September 2024	MR
Product performance evaluation	2011	MR

MR: Meets Requirements

This public report has since been amended. Amendments may have arisen because of changes to the prequalified product for which WHO has been notified and has undertaken a review. Amendments to the report are summarized in the following table, and details of each amendment are provided below.

Version	Summary of amendments	Date of report amendment
2.0	Change of ownership of the manufacturer to Arkray Healthcare Private Limited.	2015
3.0	Revisions to the labelling and packaging.	2017
4.0	Introduction of the Disposable Inverted Cup as a Sample Transfer Device as part of new configurations with product codes 55IC116-10, 55IC116-25, and 55IC116-50.	5 August 2024.
5.0	Changed the Silica Gel bag from 1 gram to 0.5 gram.	26 June 2025

Intended use:

According to the intended use from Arkray Healthcare Private Limited, "*ParaHIT f Ver 1.0-Rapid Test for P.Falciparum Malaria provides a simple, rapid, and an in vitro qualitative screening test for the detection of specific HRP II (histidine rich protein II) in human blood. It does not require additional instrument.*

The assay is intended for use by Health Care Workers / Laboratory Professionals, for an initial screening for malarial infection in symptomatic patients."

Test principle:

According to the intended use from Arkray Healthcare Private Limited, *"The test is based on the principle of immunochromatography in which nitrocellulose membrane is coated with Anti-HRP-II antibody (capture antibody) which is specific for P. falciparum. When the test sample, along with the Reaction Buffer, flows through the conjugate pad, the colloidal gold coupled with Anti-HRP-II antibodies (detection antibodies) binds to HRP-II antigens. HRP-II antigen is released from the lysed infected red blood cells of test sample. This antigen-detector antibody complex moves along the nitrocellulose membrane and binds to the corresponding immobilised antibodies to HRP-II(capture antibody), leading to the formation of the red colour band, which indicates reactive results. The control band should appear irrespective of reactive or non-reactive sample. The visualisation of control band indicates successful migration of the reaction mixture."*

Test kit contents:

Component	Product code 55IC104-10 (10 Tests/kit (T/k))	Product code 55IC104-25 (25 T/k)	Product code 55IC104-50 (50 T/kit)	Product code 55IC116-10 (10 T/k)	Product code 55IC116-25 (25 T/k)	Product code 55IC116-50 (50 T/k)
Test device	10	25	50	10	25	50
Single-use, disposable plastic pipette	10	25	50	x	x	x
Single-use, disposable inverted cup	x	x	x	10	25	50
Reaction buffer	1 x 2.5 mL bottle	1 x 6 mL bottle	1 x 12 mL bottle	1 x 2.5 mL bottle	1 x 6 mL bottle	1 x 12 mL bottle
Sterile lancets	10	25	50	10	25	50
Alcohol swabs	10	25	50	10	25	50
Instructions for use	1	1	1	1	1	1

Materials required but not provided:

- Timer
- Biohazard disposable container
- Sharps container
- Pen/pencil
- Disposable gloves.

Storage:
The test kit must be stored at 4 °C to 40°C.

Shelf-life upon manufacture:
24 months.

Warnings/Limitations

Please refer to the current version of the Manufacturer's IFU for Warning/Limitations.

Prioritization for Prequalification

ParaHIT f Ver. 1.0 Rapid Test for P. Falciparum Malaria Device was accepted for the WHO list of in vitro prequalified diagnostics on the basis of data submitted and publicly available information. Arkray Healthcare Private Limited submitted an application for prequalification of ParaHIT f Ver. 1.0 Rapid Test for P. Falciparum Malaria Device. Based on the results of the WHO product testing of malaria RDTs Round 3, ParaHIT f Ver. 1.0 Rapid Test for P. Falciparum Malaria Device was given priority for prequalification.

Dossier assessment

Arkray Healthcare Private Limited submitted a product dossier for ParaHITfVer. 1.0 Rapid Test for P.falciparum Malaria Deviceas per the *Instructions for compilation of a product dossier* (PQDx_018 v1). The information submitted in the product dossier was reviewed by WHO staff and external experts (assessors) appointed by WHO in accordance with the *internal report on the screening and assessment of a product dossier* (PQDx_009 v2). Based on the product dossier screening and assessment findings, a recommendation was made to accept the product dossier for ParaHITf Ver. 1.0 Rapid Test for P.falciparum Malaria Device for prequalification.

Manufacturing site inspection

At the time of considering the product application for Prequalification, the Manufacturer of the product had a well-established quality management system and manufacturing practices in place that would support the manufacture of a product of consistent quality.

Routine inspections of the Manufacturing site will be conducted with copies of the WHO Public Inspection Report (WHOPIR) published on the WHO Prequalification web page as per Resolution WHA57.14 of the World Health Assembly. Note that a WHOPIR reflects the information on the most current assessment performed at a manufacturing site for in vitro diagnostic products and summarises the assessment findings.

https://extranet.who.int/pqweb/vitro-diagnostics/who-public-inspection-reports

All published WHOPIRs are with the agreement of the manufacturer.
Based on the site inspection and corrective action plan review, the quality management system for the ParaHIT f Ver. 1.0 Rapid Test for P.falciparum Malaria Device meets WHO prequalification requirements.

Product performance evaluation

The third round of WHO product testing of RDTs for malaria antigen detection was completed in 2011 under the name ParaHIT-f (Device).

The product was evaluated against a *Plasmodium falciparum* cultured line panel, *Plasmodium falciparum* wild type parasite panel and a *Plasmodium falciparum* negative panel. Thermal stability was assessed after 2 months of storage at elevated temperature and humidity, and a descriptive ease of use assessment was recorded.

The panel detection score using *P. falciparum* was 84.9%, the false-positive rate was 0% and invalid rate for *P. falciparum* was 0%.

Therefore ParaHITf Ver. 1.0 Rapid Test for P. falciparum Malaria Device meets the current laboratory evaluation requirements for prequalification.

Labelling

1. **Labels**
2. **Instructions for use**

1. Labels

1.1 Labels for product codes 55IC104-10, 55IC104-25 & 55IC104-50)

1.1.1 Packaging box artwork

1.1.2 Label for Test Device Pouch

1.1.3 Labels for Reaction Buffer

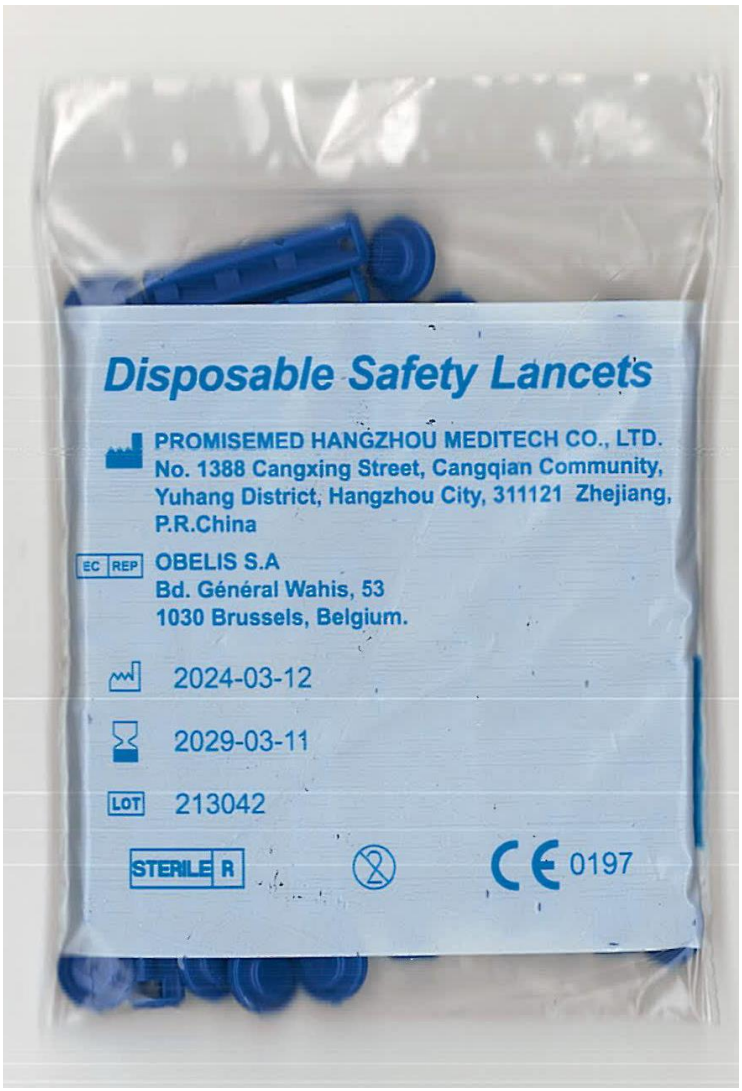
1.2 Labels for product codes 55IC116-10, 55IC116-25 & 55IC116-50

1.2.1 Packaging box artwork

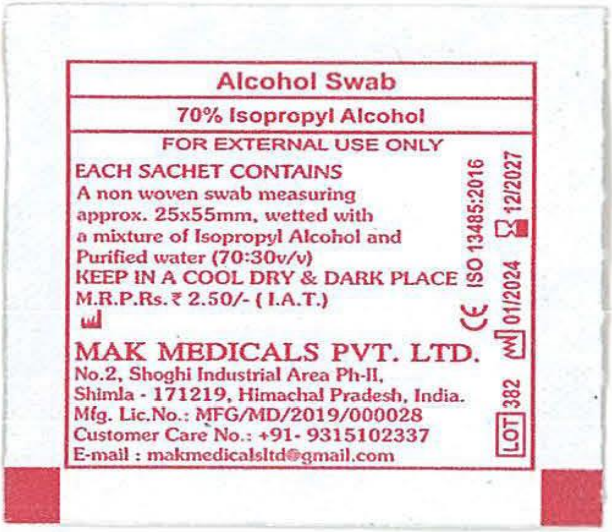
1.2.2 Label for Test Device Pouch

1.2.3 Labels for Reaction Buffer

1.3 Lancet label



1.4 Alcohol swab label



1.5 Desiccant label

To,
ARKRAY HEALTHCARE PVT LTD.
PLOT 336-338-340 , ROAD NO-3
G .I. D. C SACHIN . (SACHIN)

PRODUCT : 0.5GMOBN (COBALT FREE)
QUANTITY : 500 nos * 1 Pkt = 500 Nos
BATCH NO : AP30092022
CHALLAN No : NA
PO NO : FREE SAMPES
BOX no : 1 From,
ANIL PRODUCTS.
Navasari. Gujarat

Instructions for use[1]

[1] English version of the IFU was the one that WHO assessed. The manufacturer is responsible for ensuring correct translation into other languages.