THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

PUBLIC ASSESSMENT REPORT FOR CUPIKIT (MALARIA PF-PV RAPID DIAGNOSTIC KIT)

Version number 2.0, 18.05.2026

TMDA Headquarters, Plot No. 56/1, Block E, Kisasa B Centre, Hombolo Road, P. O. Box 1253, Dodoma – Tanzania, Telephone: +255 (26) 2961989/2061990/+255 (22) 2450512/2450751/2452108, Email: info@tmda.go.tz, Website: **www.tmda.go.tz**

Toll free: 0800110084

1. Introduction

CupiKit is a class C in-vitro diagnostic device belonging to the Immunology specialty category. CupiKit is approved in Tanzania as a kit for use by healthcare professionals.

1.1. Administrative Information

Registration number	TAN 23 MDR 0279
Brand name (if relevant)	CupiKit
Common name	Malaria Pf-Pv rapid diagnostic kit
Class of the device and rule applied	Class C as per Rule 3 for classification of In Vitro Diagnostic Devices
GMDN code and term	52311 Multiple Plasmodium species antigen IVD, kit, rapid ICT, clinical
Name and complete address of the Market Authorization Holder	Cupid Limited, A-68, MIDC (Malegon), Sinnr, Nashik-422 113, Post Code: 4221103, India.
Name and address(es) of local responsible person (LRP).	Karuda Healthcare Limited, Plot 24A, Nyerere Road, P. O. Box 21954, Dar es Salaam.

1.2. Assessment Procedure

The application for registration of CupKit was submitted on 13.04.2023. The product underwent full registration procedure assessment. Assessment was completed in 02 rounds of evaluation. CupiKit was registered on 04.12.2023.

2. Technical information

2.1. Intended use

The intended use of CupiKit as declared by the manufacturer and approved by TMDA is for qualitative detection of Histidine-Rich Protein II (HRP-II) of Plasmodium falciparum (P.f) in human whole blood. CupiKit is approved for use in healthcare settings by trained professionals only.

2.2. Device details and features

CupiKit has been registered as a kit which consists of test devices, buffer, desiccant, dropper and package insert.

CupiKit is an in vitro diagnostic device. It is used for diagnosis, of Malaria. CupiKit operates by detection of Malarial antigens, membrane strip pre-coated with Monoclonal Anti-HRP II antibody (test line pf), which is specific to the Histidine Rich Protein-II of Plasmodium falciparum, and another membrane strip with Monoclonal Anti-pLDH P. vivax antibody (test line Pv), which is specific to the lactate dehydrogenase of P. vivax species. The colorful colloidal gold conjugates of monoclonal anti-Pf, HRP 2 antibody, and monoclonal anti-Pan specific pLDH antibody complex the lysed blood sample as the test sample passes across the membrane assembly of the device following addition of assay buffer (diluent). This compound becomes immobilized on the nitrocellulose membrane's corresponding test lines, resulting in the creation of pink-purple line/s. In falciparum positive samples, a line will appear under Pf at the sample location, while in vivax positive samples, a line will appear under Pv. The test out-put is qualitative.

The type of specimen used is whole blood and is collected by venous blood collection or capillary blood specimen.

Device description
The Immunochromatography concept is used in the Malaria Pf/Pv Ag test. It includes a membrane strip pre-coated with Monoclonal Anti-HRP II antibody (test line pf), which is specific to the Histidine Rich Protein-II of Plasmodium falciparum, and another membrane strip with Monoclonal Anti-pLDH P. vivax antibody (test line Pv), which is specific to the lactate dehydrogenase of P. vivax species. The colorful colloidal gold conjugates of monoclonal anti-Pf, HRP 2 antibody, and monoclonal anti-Pan specific pLDH antibody complex the lysed blood sample as the test sample passes across the membrane assembly of the device following addition of assay buffer (diluent). This compound becomes immobilized on the nitrocellulose membrane's corresponding test lines, resulting in the creation of pink-purple line/s. In falciparum positive samples, a line will appear under Pf at the sample location, while in vivax positive samples, a line will appear under Pv. A mixed infection is indicated by the presence of a line under Pf and Pv in the test region. An additional line of goat anti-mouse IgG has been immobilized on the strip as a procedural control. This will help in the formation of a pink-purple line on the control line if the test was conducted correctly.

Pictorial diagram

	**NEGATIVE for malaria:** Only one pink-purple line appears in the control area
	**P. falciparum Positive:** Control line " C" and Test line"Pf" appears in the test window. The blood sample is infected by P. Falciparum
	**P. Vivax Positive:** Control line " C" and Test Line " Pv" appears in the test window. The blood sample is infected by P. vivax.
	**Mixed Infection:** Along with the control line "C", the Test line " Pf" and the test line " Pv" appears in the test window. The sample is infected with P.falciparum and P.vivax infection.
	**INVALID RESULT:** If control line "C" does not appear, the test is may be invalid. In this case, please repeat the test following the test procedure exactly.

2.3. Commercial presentation

There are two (2) approved commercial presentation as follows: One (1) cassette in a pouch. 50 test cassettes or 25 test cassettes are placed in a kit box.

Additional contents include pipette dropper, buffer, and package insert. The test kit is not automated and does not require any additional instrument.

2.4. Items required but not submitted

a) Watch or Timer
b) Lancets

3. Storage instructions

3.1.1. Shelf-life

24 months.

3.1.2. Storage conditions

The recommended storage conditions are 2°C -40°C

3.1.3. Shipping conditions

The recommended shipping conditions is 45±5°C and 80% RH.

4. Manufacturing site audit

The manufacturer of the device is Cupid Limited, A-68, MIDC (Malegon), Sinnar, Nashik-422 113, Maharashtra, India.

Quality audit of the manufacturing facility was conducted through site visit on 12th-13th February, 2023. The site was found to be compliant to ISO 13485 requirements.

5. Performance Evaluation

5.1. Analytical Performance

The analytical performance characteristics of the device was established through the following test parameters: precision (repeatability and reproducibility), analytical sensitivity and analytical specificity.

5.2. Clinical Performance

Clinical performance was conducted at National Public Health: Address: P.O Box 9083, Dar es salaam, Tanzania. The following parameters were tested; clinical sensitivity and clinical specificity.

Based on the result of the performance studies, it was concluded that the test sensitivity and specificity is 100% and 100% respectively. The studies further concluded that CupiKit is capable of consistently producing accurate and reliable test output.

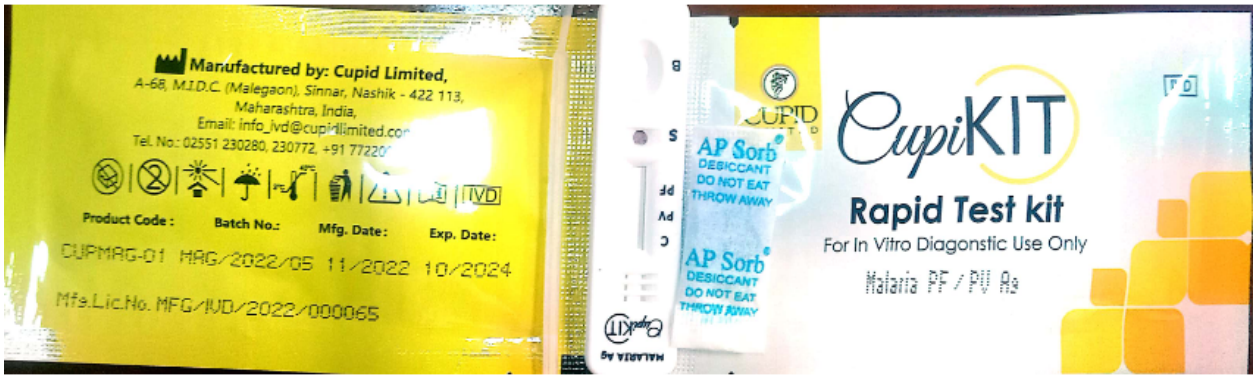
6. Product label and instructions for use

The content of the primary and secondary labels is in line with TMDA labeling requirements in terms of content, layout, and design. The label contains sufficient information for proper identification of the device and post marketing follow up of the product.

The package insert includes all the relevant information to ensure correct and safe use of the device by healthcare providers.

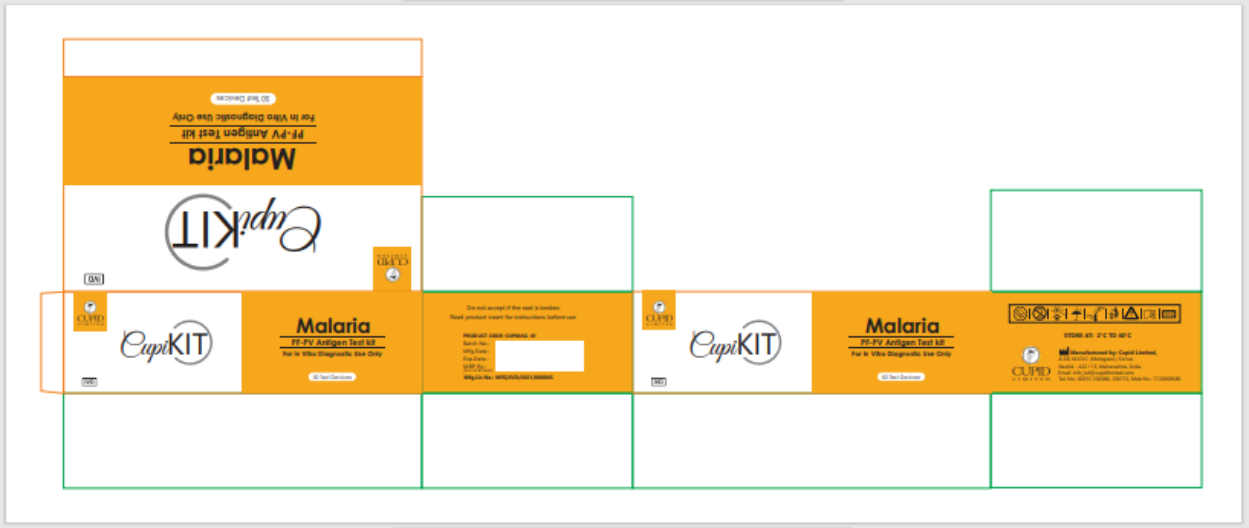
6.1. Primary pack

Mock Up Labels for Primary Pack



6.2. Secondary pack

Mock Up Labels for Secondary Pack



6.3 Instructions for use/Package insert

Instructions for use please see the last page.

7. Risk – Benefit Analysis

On basis of the data submitted, the current state of knowledge and compliance of the manufacturer to ISO 13485, the benefit of the product outweighs the risks associated with its use when used in accordance to the manufacturer's instruction. CupiKit was recommended for registration.

8. Post-approval updates

8.1. Variation applications

Reference number	Date submitted	Change requested	Recommendation	Granting date
TMDA0023/IVD/0128/A1	02/02/2024	Addition of the Cupikit malarial PF/PV Ag of 25 pack size in the market	Recommended	23/02/2024

8.2. Feedback from pharmacovigilance, post marketing surveillance and enforcement activities

Type of feedback	Impact	Response
No any recorded Adverse Event	NA	NA

8.3. Re-registration applications

NA

CHANGE HISTORY

Version number	Date	Description of update	Section(s) Modified	Approval date

CUPID LIMITED

CupiKIT

Malaria Pf-Pv Antigen Test Kit

INTENDED USE

The Malaria Pf/Pv Ag test is a chromatographic immunoassay for detecting P.falciparum specific histidine rich protein-II (Pf, HRP-II) and P.vivax specific pLDH in human blood. The test can also be used to detect and distinguish between various infections.

INTRODUCTION

Malaria is a parasite disease that can be fatal. Human malaria infections are caused by four Plasmodium parasite species: P.falciparum, P.vivax, P.ovale, and P.malariae. P.falciparum and P.vivax are the most common of them. Because of the high frequency of cerebral malaria and medication resistance associated with falciparum malaria, which causes the majority of morbidity and mortality worldwide, early detection and differentiation of malaria is critical. Because the treatment course is determined by the species, distinguishing between P.falciparum and P.vivaxis is critical for better patient care and faster recovery. The detection approach for P.falciparum malaria in Malaria Pf/Pv Ag is based on the detection of P.falciparum specific histidine rich protein-II (Pf, HRP-II), a water soluble protein released from parasitized erythrocytes of infected individuals.The presence of P.vivax specific pLDH is used in the detection technique for P.vivax malaria.

PRINCIPLE

The Immunochromatography concept is used in the Malaria Pf/Pv Ag test. It includes a membrane strip pre-coated with Monoclonal Anti-HRP II antibody (test line pf), which is specific to the Histidine Rich Protein-II of Plasmodium falciparum, and another membrane strip with Monoclonal Anti-pLDH P. vivax antibody (testline Pv), which is specific to the lactate dehydrogenase of P.vivax species. The colourful colloidal gold conjugates of monoclonal anti-Pf, HRP 2 antibody, and monoclonal anti-Pan specific pLDH antibody complex the lysed blood sample as the test sample passes across the membrane assembly of the device following addition of assay buffer (diluent). This compound becomes immobilised on the nitrocellulose membrane's corresponding test lines, resulting in the creation of pink-purple line/s. In falciparum positive samples, a line will appear under Pf at the sample location, while in vivax positive samples, a line will appear under Pv. A mixed infection is indicated by the presence of a line under Pf and Pv in the test region. An additional line of goat anti-mouse IgG has been immobilised on the strip as a procedural control. This will help in the formation of a pink-purple line on the control line if the test was conducted correctly.

PRECAUTIONS

1. Before performing the test, read the product insert carefully. The instructions must be followed to the letter in order to obtain reliable results.
2. The device is both heat and humidity sensitive. As a result, it's critical to remove the gadget from the sealed bag right before the test.
3. After the expiry date, do not use the kit.
4. Only for use in in vitro diagnostics.
5. After the test, properly dispose of all samples and kits in accordance with GLP.
6. Never use your mouth to pipette reagents or blood samples.

STORAGE AND STABILITY

The Malaria Pf/Pv Antigen test card should be stored at a temperature of 2-40°C. In the original sealed pouch, the card can also be stored at room temperature but not beyond 40°C. The card's shelf life or expiry date is printed on both the pouch as well as the carton label. Direct sunlight, moisture, and heat should be avoided when using the test kit.

SPECIMEN COLLECTION AND STORAGE

1. The testing will be carried out with freshly collected human blood from the fingertip or a vein puncture using an anticoagulant-containing sample tube.
2. Please store the specimen at 2-8°C for short-term storage

TEST PROCEDURE:

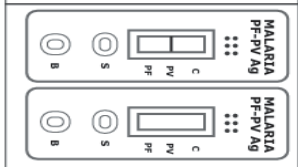
Note: After removing the test device from the pouch, it should be used immediately (within 2 minutes).

1. Using an alcohol swab, clean the fingertip and allow it to dry completely. Using a single-use lancet, prick the fingertip.
2. Using the sample dropper, collect 5 µl of blood (upto indicated marking).
3. Load the sample well "S" of the test device with 5 µl of blood.
4. Fill the assay buffer well, "B" of the test device with 3 drops (100 µl)) of assay buffer (Diluent).
5. Start the stopwatch immediately away and read the results after 20 minutes.
6. For an analysis of the test result, refer the following images.

IMPORTANT NOTE

Results should not be read beyond 20 minutes. Reading too late may give false result.

INTERPRETATION OF RESULT

	**NEGATIVE for malaria:** Only one pink-purple line appears in the control area
	**P. falciparum Positive:** Control line " C" and Test line"Pf" appears in the test window. The blood sample is infected by P. Falciparum
	**P. Vivax Positive:** Control line " C" and Test Line " Pv" appears in the test window. The blood sample is infected by P. vivax.
	**Mixed Infection:** Along with the control line "C", the Test line " Pf" and the test line " Pv" appears in the test window. The sample is infected with P.falciparum and P.vivax infection.
	**INVALID RESULT:** If control line "C" does not appear, the test is may be invalid. In this case, please repeat the test following the test procedure exactly.

LIMITATIONS OF THE TEST

1. When testing, the test procedure, precautions, and results interpretation must all be followed.
2. The Malaria Pf/Pv Ag test is a primary malaria infection screening test.
3. The test was limiting to the detection of malaria plasmodium sp. antigen. Although the test is quite accurate in detecting pLDH, there is a small chance of having a false result. If the result are suspect, further clinically accessible tests are required.

4. The test results must be evaluated in the context of epidemiology, clinical practise, and therapeutics. When it becomes necessary, the parasitological techniques of reference (microscopic examination of thick smear and thin blood films) should be explored.
5. Anticoagulants such heparin, EDTA, and citrate have no effect on the outcome of the test.
6. Do not mix different lots of reagent.
7. Malaria Pf/Pv Ag test is highly sensitive to Plasmodium falciparum and Plasmodium vivax malaria. A negative test result, on the other hand, does not rule out the possibility of P.ovale and P.malariae infection.
8. Pf, HRP-II is not secreted in the gametogony stage of P. falciparum malaria infection. As a result, the 'Pf' line may be absent in "Carriers."

REFERENCE

1. World health Organization-Geneva (2000) new perspectives malaria diagnosis.
2. Perlmann, P and Troye-Blomberg, M.2002. Malaria parasites and Disease. Malaria immunology.
3. Malcolm, J.G., et al, 2002. Genome sequence of the human malaria parasite plasmodium falciparum, Nature 419:498-511.
4. Histidine Rich Protein II: a novel Approach to malaria Drug Sensitivity Testing Antimicrobial agents and Chemotherapy, June 2002, P.1658-1664 Vol.46, No

KEY TO SYMBOLS USED			
	Manufacturer		Expiration/ Use by Date
	Do Not Reuse		Date of Manufacture
	Instructiors For Use	LOT	Lot Number
40 °C 2 °C	Temperature Limitation 2-40 °C	IVD	In Vitro Diagnostic Medical Device
NON STERILE	Non Sterile		Do Not Use If Package is Damaged
REF	Catalogue No.		Keep Dry

Please read the user manual carefully before operating to ensure proper use.

PRODUCT CODE: CUPMAG-01

DOC. NO.: IFU/IVD/010

Manufactured by: Cupid Limited,
A-68, M.I.D.C. (Malegaon), Sinnar,
Nashik - 422 113, Maharashtra, India
Email: info_ivd@cupidlimited.com
Tel. No.: 02551 230280, 230772, Mob No.: 7722009580