THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

PUBLIC ASSESSMENT REPORT FOR (CUPIKIT MALARIA PF/PAN RAPID DIAGNOSTIC KIT)

Version number 2.0, 18.05.2026

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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 0276
Brand name (if relevant)	CupiKit
Common name	Malaria Pf/Pan rapid diagnostic kit
Class of the device and rule applied	Class D as per Rule 1 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 detecting P. falciparum specific histidine rich protein-II (Pf, HRP-II) and other plasmodium species specific to pLDH in human blood. The test can also be used to detect and distinguish between various infections. 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.

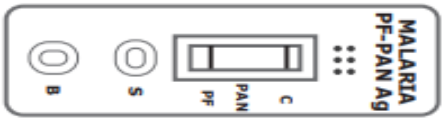
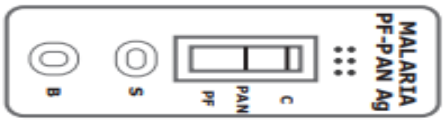
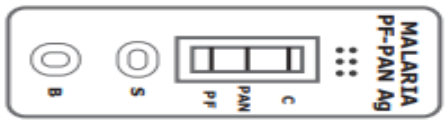
CupiKit is an in vitro diagnostic device. It is used for diagnosis, of Malaria. CupiKit operates by detection of Malarial antigens, HRP-II (histidine-rich protein II) and pLDH (Plasmodium lactate dehydrogenase) in blood sample are allowed to react with the anti-HRPII and anti-pLDH monoclonal antibody coupled gold conjugate followed by reaction with anti-HRP-II antibody (Pf, test line-1) and/or anti-pLDH antibody (Pan, test line-2) in the test lines through lateral flow chromatographic immunoassay. 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 test device contains the following; nitrocellulose membrane strips, sample pad, conjugate releasing pads, absorbent pad, plastic cassette for lateral flow assay, laminated pouch, specimen transfer device and specimen volume. 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 for other plasmodium species antibody (test line PAN), which is specific to the lactate dehydrogenase of other plasmodium 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 PAN positive samples, a line will appear under PAN. A mixed infection is indicated by the presence of a line under Pf and PAN in the test region.

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
	**PAN Positive:** Control line " C" and Test Line " PAN" appears in the test window. The blood sample is infected by PAN (P. vivax, P. Malaria, P.Ovalae, P. knowlesi).
	**Mixed Infection:** Along with the control line "C", the Test line " Pf" and the test line " PAN" appears in the test window. The sample is infected with P.falciparum and PAN 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 pouches or 25 pouches 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

The approved shelf-life is 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 at 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.

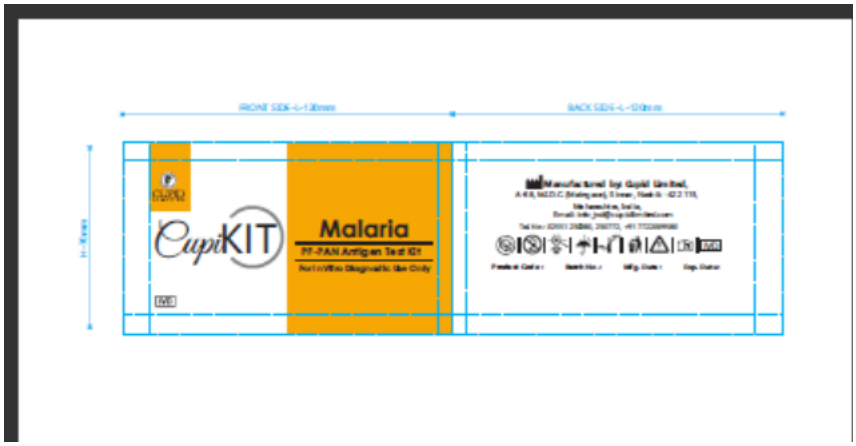
6. Product label and instructions for use

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 user manual, package insert, instructions for use includes all the relevant information to ensure correct and safe use of the device by healthcare providers.

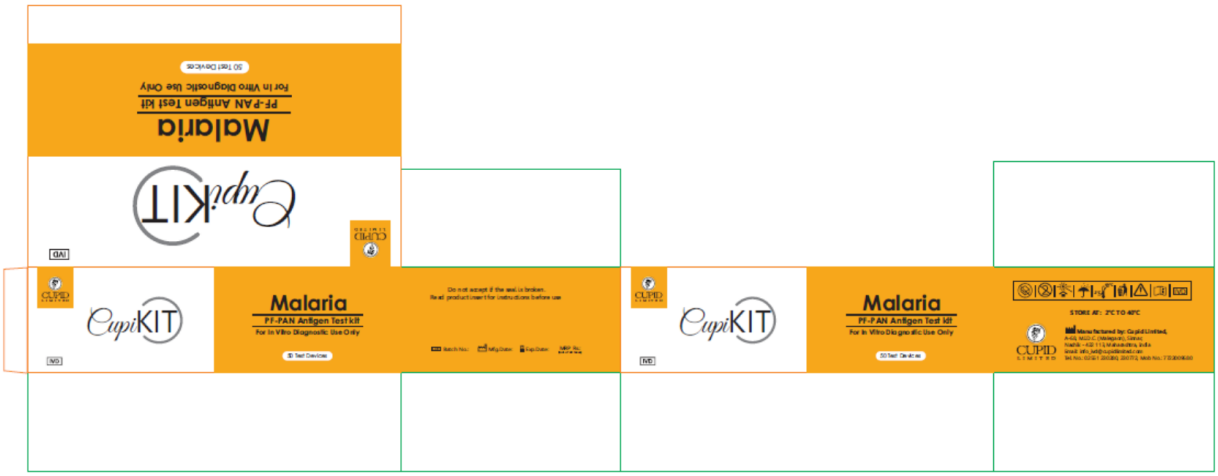
6.1. Primary pack

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 can be accessed on 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-PAN Antigen Test Kit

INTENDED USE

The Malaria Pf/PAN Ag test is an immunochromatographic assay for qualitative detection between plasmodium falciparum Histidine-Rich protein-II (HRP-II) and plasmodium species (plasmodium falciparum, P. vivax, P. ovale and P. malaria) lactate dehydrogenase (pLDH) in human whole blood. This test is intended for professional use.

INTRODUCTION

Malaria Pf/PAN Antigen (Ag) is a chromatographic immunoassay kit for rapid qualitative determination of malaria infection using whole blood specimen. Malarial antigens, HRP-II (histidine-rich protein II) and pLDH (Plasmodium lactate dehydrogenase) in blood sample are allowed to react with the anti-HRPII and anti-pLDH monoclonal antibodycoupled gold conjugate followed by reaction with anti-HRP-II antibody (Pf, test line-1) and/or anti-pLDH antibody (Pan, test line-2) in the test lines. When the blood sample is infected with malaria, a visible line appears in the test region on the membrane. Malaria Pf/Pan Ag can also discriminate between P. falciparum and P. vivax/P. malariae/P. ovale/P. knowlesi.

MATERIALS PROVIDED

Malaria Pf/PAN Ag kit contains the following items:

1. Malaria Pf/PAN Ag device
2. Assay buffer
3. Instruction manual/ product Inserts

MATERIALS REQUIRED BUT NOT PROVIDED

1. Lancets (for finger stick whole blood only)
2. Watch or Timer

STORAGE AND STABILITY

1. Malaria Pf/Pan Ag kit should be stored between 2 to 40℃.
2. Expiration date of this kit is 24 months after its manufacture date.

PRECAUTIONS

1. The device is sensitive to humidity as well as to heat. So, it's very important to take off the device from the sealed pouch when it use.
2. Do not use the kit after the expiration date.
3. For in vitro diagnostic use only.
4. Wear protective gloves while handling samples and wash hands thoroughly after the test.
5. Dispose all the samples and kits properly after test, in accordance with GLP.
6. Do not pipette reagent or blood by mouth.

SPECIMEN COLLECTION AND STORAGE

1. The test should be performed with freshly collected human blood collected from the fingertip or by venipuncture using sample tube containing anti-coagulant.
2. For the short term storage, please keep the specimen at 2-8℃, for the long term storage, please keep the sample below -20˚C.

TEST PROCEDURE

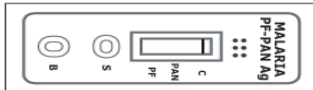
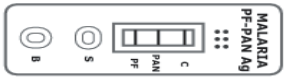
Note: After removing the test device from the pouch, it should be used immediately (within 2 minutes).

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.

INTERPRETATION OF RESULT

NEGATIVE: Only the control band is visible. Negative result indicates that there is no malaria infection in the sample.
POSITIVE: Along with the control band, if the Pf or the Pf+Pan band appear together, the blood sample is infected with P. falciparum. If only the Pan band appears, the blood sample is infected by P. vivax(in usual) or P. malaria/P. ovalae/P.knowlesi (in rare).
INVALID: If control band does not appear, the test is maybe invalid. In this case, please repeat the test,

Following the test procedure exactly.

	**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
	**PAN Positive:** Control line " C" and Test Line " PAN" appears in the test window. The blood sample is infected by PAN (P. vivax, P. Malaria, P.Ovalae, P. knowlesi).
	**Mixed Infection:** Along with the control line "C", the Test line " Pf" and the test line " PAN" appears in the test window. The sample is infected with P.falciparum and PAN 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

Malaria Pf/Pan Ag is designed for primary screening test of malaria infection. This kit can provide fast and easy way to get a result, but do not completely exclude the possibility of false positive or false negative result caused by various factors. So, refer to the result of this kit, please make a final decision with clinical manifestation, other test results, and doctor's view, collectively.

REFERENCES

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

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.

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

PRODUCT CODE: CUPMAP-01
DOC. NO.: IFU/IVD/009