PATHKITS

SIMPLE Malaria Pf RAPID Test

Product Code: **PKRK008**
Kit Contents (**25 Kits**)
Shelf Life: 24 Months

Kit Components	Quantity (Units)
Test cassettes	25
Assay Buffer	1 Bottle
Sample Dropper (Inverted Cup (5µl))	25
Lancet	25
Alcohol Swabs	25
IFU	1

Introduction

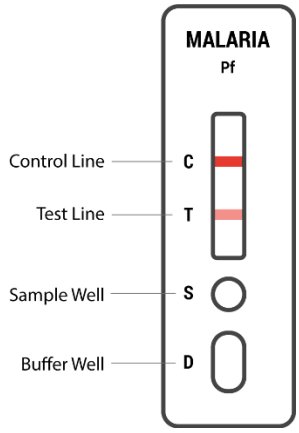
Malaria is caused by the parasitic protozoan Plasmodium. It is a vector-borne disease which is transmitted from person to person via bites from infected *Anopheles* mosquitoes. Following a mosquito bite the parasites multiply in the liver and subsequently infect red blood cells**.** remains one of the most serious tropical and subtropical diseases in many countries of the world. bite of infected mosquitoes. Humans are hosts for four main *Plasmodium* species: *P. falciparum*, P. *vivax, P. ovale,* and *P. malariae*. In humans the parasite called sporozoites migrate to the liver and release another form called merozoites. Globally, ~50% of infections are caused due to *P. vivax, ~40%* are *due to P. falciparum,* ~ 10% due to *P. malariae* and <1% to *P. ovale*. The disease now occurs in more than 90 countries worldwide, and it is estimated that there are over 500 million clinical cases and 2.7 million malaria-caused deaths per year. At present, malaria is diagnosed by looking for the parasites in a drop of blood. Blood will be put into a microscope slide and stained so that the parasites will be visible under a microscope.

Intended Use

For the rapid qualitative determination of Malaria *P. falciparum* specific histidine rich protein-2 (Pf HRP-2) in human blood as an aid in the diagnosis of Malaria infection. The Malaria Pf Rapid Test is a visual, rapid and sensitive solid phase immunochromatographic assay for the qualitative differential detection of *P. falciparum* (HRP-2) antigen in the blood sample. The kit is intended for professional use and as a screening test. All reactive samples should be confirmed by a supplemental assay like microscopic examination of thick smear and thin blood films. It assists trained competent users in detecting plasmodium infections.

Test Principle

The simple malaria Pf (HRP-2) antigen test kit contains a strip with pre-coated two test lines and one control line immobilized onto a nitrocellulose strip. One monoclonal anti-HRP-2 antibody specific to P. *falciparum* species coated on the test line. The control line consists of goat anti rabbit- lgG. After addition of blood samples and assay buffer to the test strip the red blood cells get lysed. If the sample contains *P. falciparum* the colloidal gold conjugated monoclonal antibodies in the lysed sample. This complex migrates through the nitrocellulose strip by capillary action. When the complex meets the line of the corresponding immobilized antibody, the complex is trapped forming a colored band which confirms a reactive test result.



Absence of a coloured band in the test region indicates a non-reactive test result. A procedural control line should always develop at the 'C' region to indicate that the test has been carried out correctly.

Warnings and Precautions

1. For professional *in vitro* diagnostic use only. Do not use it after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all the specimens as if they contain infectious agents.
4. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
6. Humidity and temperature can adversely affect results.
7. Do not open the sealed pouch, unless ready to conduct the assay.
8. Do not use the components in any other type of test kit as a substitute for the components in this kit.
9. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.

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10. Handle the negative and positive controls in the same manner as the patient specimens.
11. Do not reuse the test device.
12. Use separate sample dropper or pipette tips for each sample in order to avoid cross contamination of samples which could cause erroneous results.

Sample collection and Storage Instructions

1. Collect the whole blood in a collection tube (containing EDTA, citrate or heparin or oxalate or Tri-sodium Citrate as suitable anticoagulants) by venipuncture.
2. If samples are not immediately tested, they should be stored at 2-8℃. For storage periods more than 3 days, freezing is recommended. They should be brought to room temperature prior to use.
3. Fresh blood from finger prick may also be used as a test sample.
4. Clotted contaminated blood samples should not be used for performing the test. Fresh blood from finger prick or puncture may also be used as a test specimen.

Materials Required but not provided

1. Timer or Stopwatch.
2. PPE and other consumables for collection and disposal of samples.

Storage and Stability

1. This kit can be stored between 2-40 ℃. Do not freeze the kit.
2. The kit is stable upto expiration date as printed on the pouch.
3. Do not use it beyond the expiry date.

Limitations

1. As with all the diagnostic tests, the interpretation of assay results must always be correlated with clinical findings.
2. Any modifications to the given procedure or use of other reagents will invalidate the test procedure.
3. It is intended for screening use only, not for use in diagnostic procedures.
4. The Simple Malaria Pf Rapid Test is limited to the detection of malaria antigen Pf Although the test is very accurate in qualitative detecting pLDH, a very low occurrence of false results are obtained.
5. The intensity of the test line does not have linear correlation with virus titer in the specimen.
6. As with all diagnostic tests, the test result should not be based on the results obtained by a single test, but should only be made by the physician after all clinical and laboratory findings have been assessed.
7. The Simple Malaria Pf Rapid Test device detects both viable and non-viable HRP-2 antigens.

Test Procedure

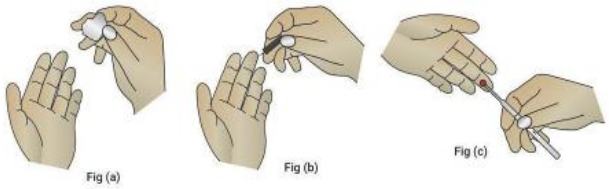
1. Bring the kit components and specimen to be tested to room temperature before testing.
2. Open the test card from the pouch prior to use and place it on a flat and dry surface. The test should be performed immediately after removing the test card from the pouch.
3. Tighten the vial cap of the assay buffer provided along with the kit in the clockwise direction to pierce the nozzle of the dropper bottle.

4. Take 5µl anticoagulated whole blood into the sample well. Do not use excess blood.
5. Add 4 drops of assay buffer into well.

Use finger prick blood samples as described below.

Finger Prick Sample Collection:

- Clean the patient's finger tip with the alcohol or spirit. Wait until the finger has completely dried.
- Prick the patient's finger with the lancet, perpendicular to the lines of the finger print. Make sure a well formed drop of blood is present on the tip of the finger.



- Take the sample dropper and collect 5µl of blood by dipping the tip of the sample dropper into the blood drop and immediately place the tip of the sample dropper in the sample well. Press the tip of the dropper onto the sample pad in the sample well to ensure that the complete volume of whole blood has been transferred to the strip.

6. Add 4 drops of the assay buffer in the buffer well. Screw cap the vial after use.
7. Allow the reaction to occur for 15 minutes.
8. Observe the results in 15 minutes. Do not read the result after 20 minutes. Reading beyond prescribed time may give false results.
9. Discard the test card immediately after reading the results at 20 minutes.

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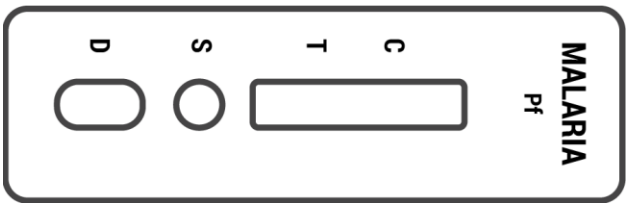
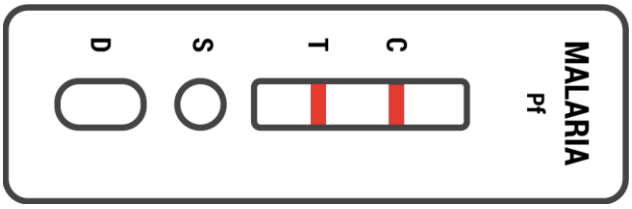


Interpretation of results

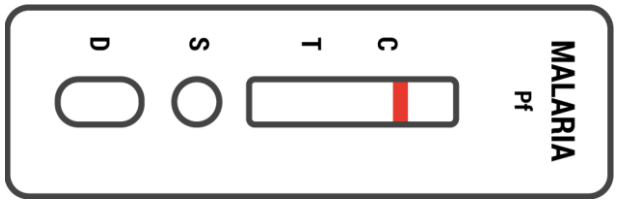
Positive Results

- Appearance of two coloured lines, Test line region (T) & Control region (C) indicates that the sample is reactive for P. falciparum. The pf HRP II present in the sample reacts with the pf HRP II conjugate and move through the test strip where the pf HRP II is captured by the anti -P falciparum specific HRP II



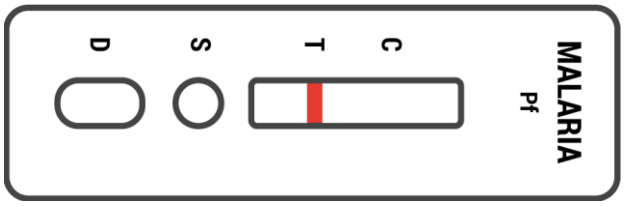
Negative Result

- Appearance of only one coloured line at Control (C) region indicates that the sample is nonreactive for P. *falciparum.*



Invalid Results

Control line does not appear in the Control (C) region. If no C line develops, the assay is invalid regardless of color development on the T line. Repeat the assay with a new device. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. If the problem persists, discontinue using the test kit immediately and contact your local distributor



Internal Quality Control

We thought there is an internal procedural line in the test device of control region, the use of external controls is strongly recommended as good laboratory testing to confirm the fast procedure and to verify proper fast performance. Positive and negative control should give the expected result when testing the positive and negative control, the same assay procedure should be adopted.

Performance Characteristics

Simple Malaria Pf rapid test kit as tested with positive and negative clinical samples and compared by microscopic examination of whole blood shows sensitivity Pf - 98.3%.

Sample	Total sample	Microscopic results		Simple Malaria Pf		Sensitivity	Specificity
				Test Result			
		+ve.	-ve.	+ve	-ve		
P. falciparum	120	120	-	118	3	98.3%	-
Malaria Negative	200	-	200	1	199	-	99.5%

Technical Assistance

For customer support, please contact our Technical Support:
PathKits Healthcare Pvt Ltd, Plot 28, 29 Sector 18(P),
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Central Drugs Standard Control Organisation

Directorate General of Health Services

Ministry of Health & Family Welfare

(Medical Device & Diagnostic Division)

FDA Bhawan, Kotla Road
New Delhi-110002
Phone No-011-23236965
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File No. : NZ/MD/2021/000177

Dated : 10-MAY-2022

M/s PATHKITS HEALTHCARE PRIVATE LIMITED,
Plot No-28-29, Sector-18
Gurgaon, Gurgaon, Haryana (India) - 122001
Telephone No.: 8802872273 FAX: 8802872273

Sub:- Licence to manufacture for Sale or for Distribution of Class C or Class D medical devices in Form MD-9 under Medical Device Rules, 2017- regarding.

Sir,

Manufacturing licence No. MFG/IVD/2021/000068 in Form MD-9 is hereby forwarded to you. This licence is subject to following conditions:

1. Licence shall be produced when requested by the Medical Device Officer or any other senior officer under the control of Central Licensing Authority.
2. The licence holder shall inform the Central Licensing Authority of the occurrence of any suspected unexpected serious adverse event and action taken thereon including any recall within fifteen days of such event coming to the notice of licence holder
3. The licence holder shall obtain prior approval from the Central Licensing Authority, before any major change as specified in the Sixth Schedule is carried out and the Central Licensing Authority shall indicate its approval or rejection within forty five days and in case where no communication is received within the stipulated time from such Authority, such change shall be deemed to have been approved
4. The licence holder shall inform any minor change as specified in the Sixth Schedule to the Central Licensing Authority within a period of thirty days after such minor change take place
5. The licence holder shall carry out test of each batch of product manufactured prior to its release for compliance with specifications either in his own laboratory or in any other laboratory registered under sub-rule (3) of rule 83;

6. The licence holder shall, on being informed by the Central Licensing Authority that any part of any lot of the medical device has been found not conforming with the provisions specified under the Act and these rules, and on being directed so to do by such licensing authority, withdraw the remainder of that lot from sale and, so far as may, in the particular circumstances of the case, be practicable, recall the issues already made from that lot;
7. The licence holder shall maintain an audit or inspection book in Form MD-11 to enable the Notified Body or Medical Device Officer to record his observations and non-conformity, if any;
8. The licence holder shall maintain at least one unit of sample from each batch of invasive medical device and in vitro diagnostic medical device manufactured for reference purpose for a period of one hundred and eighty days after the date of expiry of such batch;
9. The licence holder shall maintain records of manufacturing and sales which shall be open to inspection by a Medical Device Officer;
10. The medical device, when offered for sale, shall be accompanied by either its package insert or user manual, wherever applicable;
11. The manufacturing or testing activity of medical device shall be undertaken only under the direction and supervision of the competent technical staff;
12. If the manufacturer has stopped manufacturing activity or closed the manufacturing site for a period of thirty days or more, the same shall be intimated to the Central Licensing Authority.

Yours faithfully

VENUGOPAL G SOMANI

Licensing Authority

Seal/Stamp

Digitally signed by VENUGOPAL G SOMANI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=DRUGS CONTROLLER GENERAL (INDIA), postalCode=110084, st=DELHI, serialNumber=e97f241a90c0bba41522525ffca0705074b4997e6b2f4b5c8d81cf282adeaf5d, cn=VENUGOPAL G SOMANI
Date: 2022.05.10 16:55:14 +05'30'

FORM MD-9

[See sub-rule (1) rule 25]

सत्यमेव जयते

Licence to Manufacture for Sale or for Distribution of Class C or Class D medical device

Licence Number: MFG/IVD/2021/000068

Endorsement No. 5

1. M/s PATHKITS HEALTHCARE PRIVATE LIMITED, Plot No-28-29, Sector-18Gurgaon, Gurgaon, Haryana (India) - 122001 Telephone No.: 8802872273 FAX: 8802872273 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s PATHKITS HEALTHCARE PRIVATE LIMITED, 4th Floor, 28, 29 Electronic City, Sector -18, Gurgaon, Haryana (India) - 122001 Telephone No.: 8588869343 FAX: 8588869343

2. Details of medical device(s) [Annexed]

3. The names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned medical device(s): As per records maintain by the manufacturer

4. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)
1	Generic Name:Malaria Pf Rapid Test Kit Model No.:PKRK008 - NA Intended Use:The Malaria Pf Rapid Test is a visual, rapid and sensitive solid phase immunochromatographic assay for the qualitative differential detection of P. falciparum (HRP-2) antigen in the blood sample. Class of medical device:Class C Material of construction:NA Dimension(if any):NA Shelflife:24 Months Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):SIMPLE Malaria Pf Rapid Test Kit

Place:

Date:10-May-22

VENUGOPAL G SOMANI

Digitally signed by VENUGOPAL G SOMANI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, o[illegible], pseudonym=112[illegible]32c456d249073e55e953d9cb5b58748ee3113c, postalCode=110002, st=DELHI, serialNumber=e97f241aa0c0bba41522525ffca0705074b4997e6b2f4b5c8d81cf282adeaf5d, cn=VENUGOPAL G SOMANI
Date: 2022.05.10 16:55:04 +05'30'

Central Licensing Authority