PATHKITS

SIMPLE Malaria Pf/Pv RAPID Test

Product Code: **PKRK006**
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 Swab	25
IFU	1

Introduction

Malaria remains one of the most serious tropical and subtropical diseases in many countries of the world. It is characterized by fever, chills and anaemia and is caused by a parasite that is transmitted from one human to another by the bite of infected *Anopheles* 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.

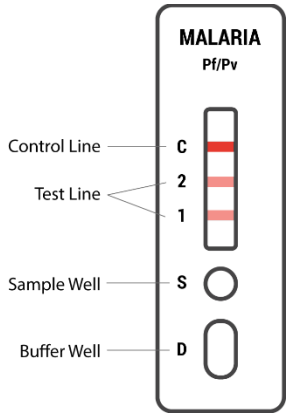
Intended Use

For the rapid qualitative determination of Malaria *P. falciparum* specific histidine rich protein-2 (Pf HRP-2) and Malaria *P.vivax* specific lactate dehydrogenase (pLDH) in human blood as an aid in the diagnosis of Malaria infection. The Malaria Pf/P Rapid Test is a visual, rapid and sensitive solid phase immunochromatographic assay for the qualitative differential detection of *P. falciparum* (HRP-2) and *P. vivax* malaria antigen in the blood sample. The test may also be used for the differentiation of *P. falciparum* and *P. vivax*. Infection. 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)/Pv (pLDH) 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 test line 1 and another monoclonal anti-pLDH antibody specific to *P. vivax* coated onto test line 2. The control line consists of goat anti rabbit- IgG. After addition of blood samples and assay buffer to the test strip the red blood cells get lysed. If the sample contains *P. falciparum* or *P. vivax* or both, the colloidal gold conjugated monoclonal antibodies complexes the HRP-2 / *P. vivax* specific pLDH 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.

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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.
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 up to 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/Pv Rapid Test is limited to the detection of malaria antigen Pf/Pv. Although the test is very accurate in qualitative detecting pLDH and HRP-2, 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/Pv Rapid Test device detects both viable and non-viable HRP-2 antigens. Test performance depends on antigen loaded in the sample. A positive test does not rule out the possibility that other pathogens may be present.
8. Performance of the test has not been established for monitoring antiviral treatment of HRP-2 infection.

Test Procedure

1. Bring the kit components and specimen to be tested to room temperature before testing.
2. Open the test card and desiccant from the pouch prior to use and place it on a flat and dry surface. Check the color of the desiccant, it should be blue. Note: Do not use the card if the desiccant is pink in color.
3. The test should be performed immediately after removing the test card from the pouch.
4. 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.

5. Take a 5µl anticoagulated blood sample and mix evenly by gently using the sample dropper.
6. Add 4 drops of assay buffer into well.

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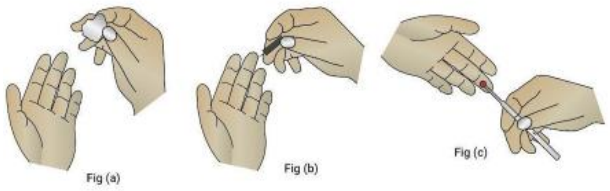
Use finger prick blood samples as described below.

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.



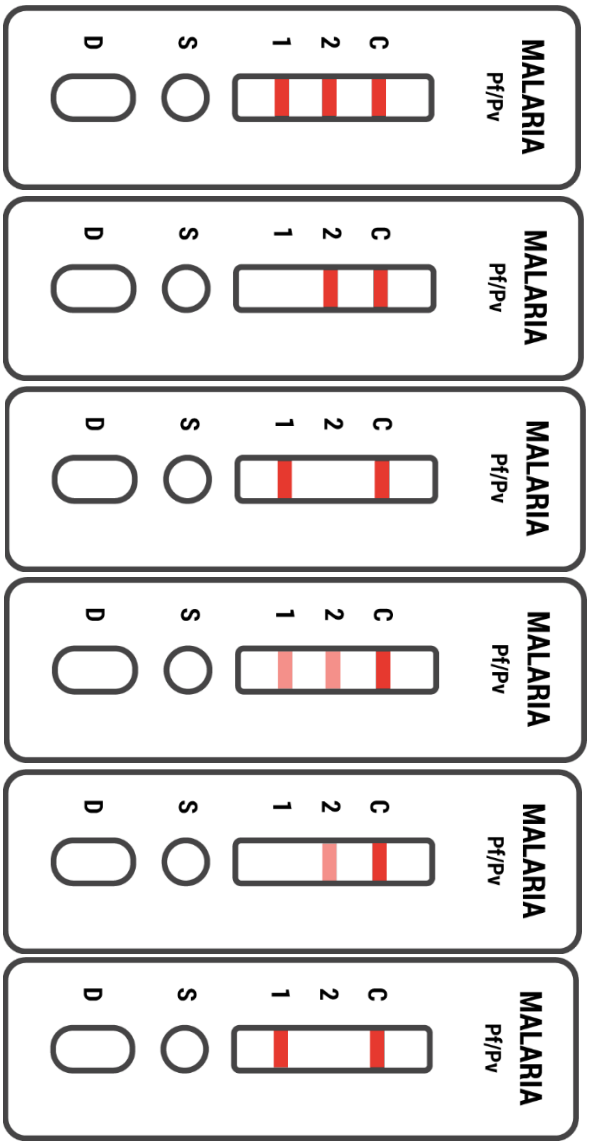
- Take the sample dropper and collect 5µl of blood by dipping the tip of the sample dropper into the blood drop and immediately place the tip of the sample dropper in the sample well. Press the tip of the dropper onto the sample pad in the sample well to ensure that the complete volume of whole blood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

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

Interpretation of results

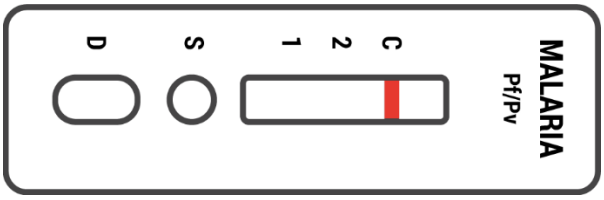
Positive Results

- Appearance of three coloured lines, one each in Pf region (1), Pv region (2) & Control region (C) indicates that the sample is reactive for *P. falciparum* and *P. vivax.*
- Appearance of two coloured lines, one each at 2 & C region only indicates that the sample is reactive for *P. vivax* only.
- Appearance of two coloured lines one each at 1 & C region only indicates that the sample is reactive for *P. falciparum* only. A difference of intensity in colour may occur between the test line & control line depending on the concentration of HRP-2 / pLDH in the sample but this does not affect the interpretation of the results.
- Depending on the concentration of pLDH/HRP-2, positive results may be observed within 60 seconds. However, to confirm a negative result the test result should be read only at 20 minutes.



Negative Result

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



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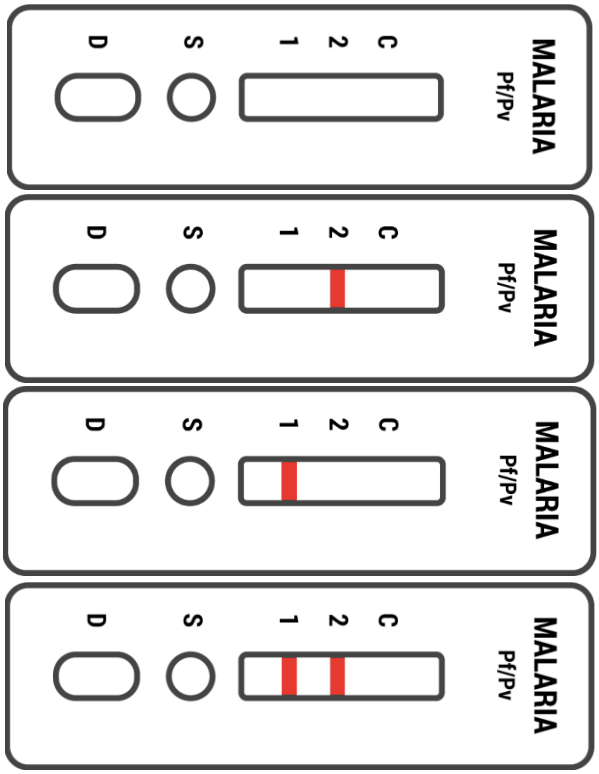
Invalid Results

Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. 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/Pv rapid test kit as tested with positive and negative clinical samples and compared by microscopic examination of whole blood shows sensitivity Pf - 96.9%,
Pv - 95.8%.

Sample	Total sample	Microscopic results			Simple Malaria Pf/Pv			Sensitivity	Specificity
		Test Result							
		+ve		-ve	+ve		-ve		
		Pf	Pv		Pf	Pv			
Pf	130	130	-	-	126	-	4	96.9%	-
Pv	120	-	120	-	-	115	5	95.8%	-
Malaria -ve	200	-	-	200	-	1	199	-	99.5%

Technical Assistance

For customer support, please contact our Technical Support:

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