PATHKITS

SIMPLE Malaria Pf/Pan RAPID Test

Product Code: **PKRK007**
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

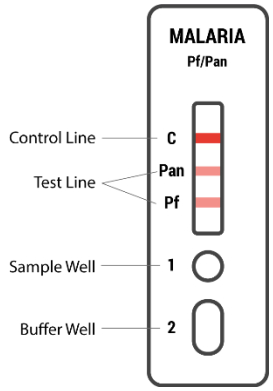
Malaria remains one of the most serious tropical and subtropical diseases in many countries of the world. It is characterized by fever, chills and anemia and is caused by a parasite that is transmitted from one human to another by the bite of infected *Anopheles* mosquitoes. Humans are hosts for four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

Simple Malaria Pf/Pan Card is a rapid qualitative and sensitive chromatographic immunoassay based on antigen detection. It is used as an aid in differential identification of infection with HRP-2 (Histidine Rich Protein-2) specific *P. falciparum* and pLDH (Plasmodium Lactate Dehydrogenase) specific *Plasmodium* sp. (*P. vivax* / *P. malariae* / *P. ovale*) in human whole blood specimens. The kit is intended for professional use and as a preliminary test and not to be used for carriers. All reactive samples should be confirmed by a supplemental assay like microscopic examination of thick smear and thin blood films.

Test Principle

Simple Malaria Pf/Pan Card is a membrane-based immunoassay for the detection of *P. falciparum/ P. vivax/ P. malariae/ P. ovale* antigens in the whole blood. It contains a membrane pre-coated with Pf specific monoclonal anti-HRP-2 antibodies and anti-pan specific pLDH antibodies. During testing, the whole blood specimen reacts with the dye conjugate, pre-coated on the nitrocellulose strip. The mixture then migrates upward on the membrane by capillary action, reacts with anti-Histidine-Rich Protein II (HRP-II) antibodies on the membrane on Pf test Line region and with anti-Aldolase antibodies on the membrane on the Pan line region.



If the specimen contains HRP-II or Plasmodium-specific Aldolase or both, a colored line will appear in Pf line region or Pan line region or two-colored lines will appear in Pf line region and Pan line region. The absence of the colored lines in Pf line region or Pan line region indicates that the specimen does not contain HRP-II and/or Plasmodium-specific Aldolase. To serve as a procedure control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane absorption has occurred. The test contains an internal control (C line) which should exhibit a colored line regardless of color development on the T line. If the C line does not develop, the test result is invalid and the specimen must be retested with a new device.

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.

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.

Materials Required but not provided

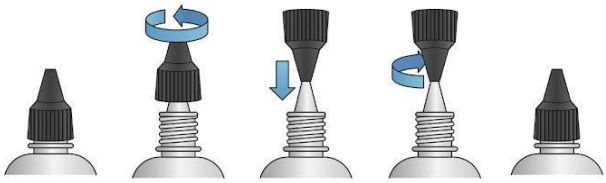
1. Timer or Stopwatch.
2. PPE and other consumables for collection and disposal of samples.

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/Pan Rapid Test is accurate in detecting HRP-2 specific to P. falciparum or pLDH specific to Plasmodium species (*P. falciparum/ P. vivax/ P. malarie/ P. Ovale*), a low incidence of false results can occur.
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. Since the HRP-2 persists for upto a fortnight even after successful therapy, a positive test result does not indicate a failed therapeutic response.
8. In *P. falciparum* malaria infection, HRP-2 is not secreted in the gametogony stage. Hence, in 'carriers', the HRP-2 test line (Pf) may be absent.
9. The possibility of resistant strain of malaria should always be considered if the reaction of the test remains positive with the same intensity after 5-10 days post treatment.
10. Patient with rheumatoid factors, anti-nuclear antibody or dengue may give false positive results.

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 desiccant is pink in color.
3. The test should be performed immediately after removing the test card from the pouch.
4. Label the patient's name or identification number on the test card.
5. 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.

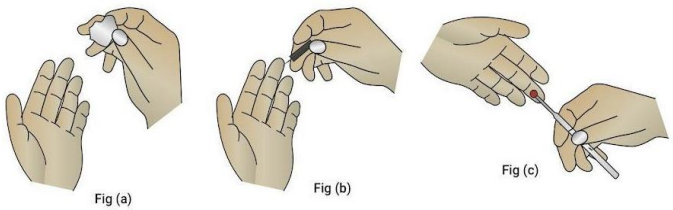


6. Take 5µl anticoagulated whole blood into the sample well. Do not use excess blood.
7. Add 4 drops of assay buffer into well.

Use finger prick blood samples as described below.

Finger Prick Sample Collection:

- Clean the patient's fingertip 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

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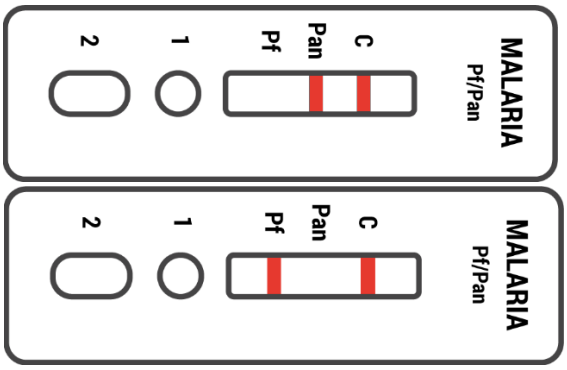
well. Press the tip of the dropper onto the sample pad in the sample well to ensure that the complete volume of whole blood has been transferred to the strip.

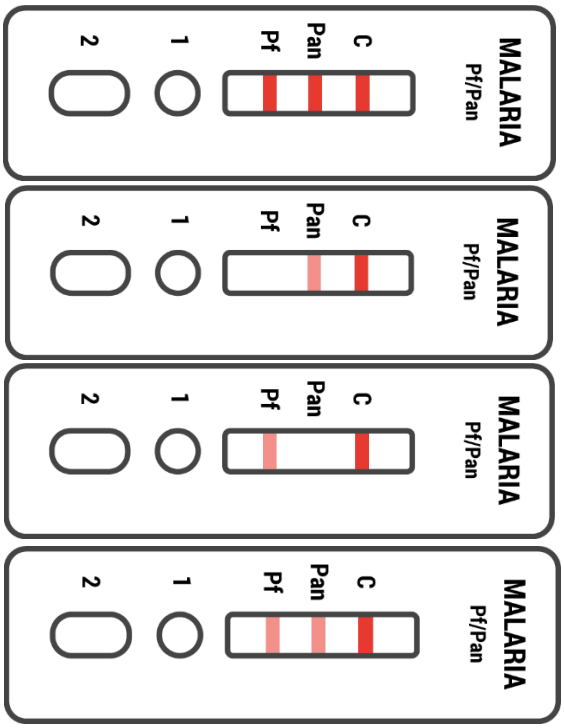
8. Add 4 drops of the assay buffer in the buffer well. Screw cap the vial after use.
9. Allow the reaction to occur for 15 minutes.
10. Observe the results in 15 minutes. Do not read the result after 20 minutes. Reading beyond prescribed time may give false results.
11. Discard the test card immediately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

Interpretation of results

Positive Results

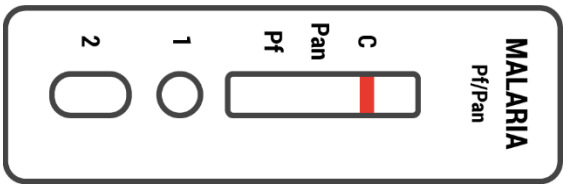
- Appearance of three coloured lines one each in Pf region, Pan region & Control region (C) indicates that the sample is reactive for *P. falciparum* or mixed infection of Pf and P.v (or *P. malarie*, *P.ovale*).
- Appearance of two coloured line one each at Pan & C region only indicates that the sample is reactive for *P. vivax*/ *P. malariae*/ *P. ovale* only.
- Appearance of two coloured line one each at Pf & C region only indicates that the sample is reactive for *P. falciparum* only.
- A difference of intensity in colour may occur between both the test lines (Pf & Pan) and between the test lines & control line depending on the concentration of pLDH & HRP-2 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.
- Consider a faint test line also as a positive result.





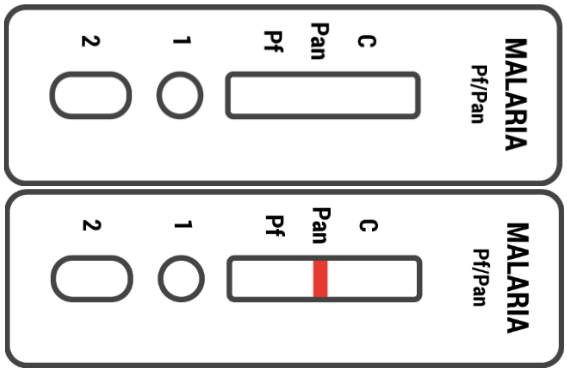
Negative Result

- Appearance of only one coloured line at Control (C) region indicates that the sample is non-reactive for *P. falciparum* and other *Plasmodium* Species (*P. vivax* / *P. malariae* / *P. ovale*).



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.



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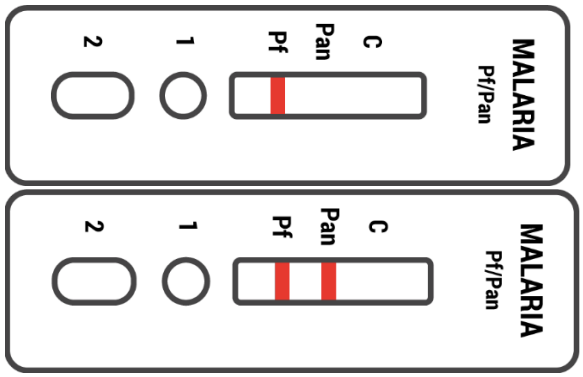

Technical Assistance

For customer support, please contact our Technical Support:

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Internal Quality Control

The Simple Malaria Pf/Pan test test device has test lines ("Pan", "Pf") and control line ("C") on the surface of the device. Neither the test line nor the control line as visible in the result window before applying a specimen. The control line is used for procedural control and shows only that the diluent has been applied successfully and that the active ingredients of the main components on the strip are functional, but is not a guarantee that the specimen has been properly applied and does not represent a positive specimen control.

Performance Characteristics

Simple Malaria Pf/Pan rapid test kit as tested with positive and negative clinical samples and compared by microscopic examination of whole blood shows sensitivity Pf - 96.8%, Pan - 96.0%.

Sample	Total sample	Microscopic results			Simple Malaria Pf/Pan			Sensitivity	Specificity
					Test Result				
		+ve		-ve	+ve		-ve		
		Pf	Pan		Pf	Pan			
Pf	125	125	-	-	121	-	4	96.8%	-
Pan	150	-	150	-	-	144	6	96.0%	-
Malaria Negative	200	-	-	200	-	1	199	-	99.5%

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