Malaria P.f/Pan Antigen Rapid Test

Cat. No.: S005-07

In vitro Diagnostics

INTENDED USE

Sensit Malaria P.f/PAN Antigen Rapid Test Kit is a qualitative immunochromatographic assay for the simultaneous and differential detection of Malaria P. falciparum and other Plasmodium (P.vivax, P. malariae, P. ovale) in human blood. The Sensit Malaria P.f/PAN Antigen test is only intended for initial screening and reactive samples should be confirmed by a supplemental assay.

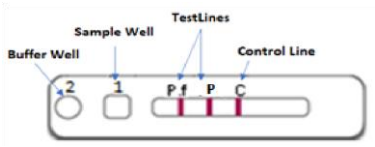
SUMMARY &TEST DESCRIPTION

Four species of *Plasmodium* parasites are responsible for Malaria infections in human population: *P.falciparum,P.vivax,P.ovale,P.malaria*. Of these, *P.falciparum* is responsible for most of the morbidity and mortality worldwide. The period of incubation, symptoms and duration of attack varie with the specious and the individual's level of acquired immunity. Early detection and differentiation of malaria is there for of paramount importance due to the incidence of cerebral malaria and associated drug resistance. *P.falciparum* histidine rich protein too

(PfHRP2) is a water soluble protein that is released from parasitized erythrocytes of infected individuals and is species specific. It differentiates the infection from the other malaria species, which can be detected by PAN malaria plasmodium Lactate Dehydrogenase (pLDH) released from parasitized red blood cells.

TEST PRINCIPLE

Sensit Malaria Pf/PAN Antigen Rapid Test works on chromatographic immunoassay. Basic components of test strip includes: a) Conjugate pad, which contains a mixture of Anti-malaria Pf antibody and Anti-malaria PAN antibody, colloidal gold conjugated; b) a nitrocellulose membrane strip containing three coated lines Pf: Anti-malaria Pf antibody , P: Anti-malaria PAN antibody and C: Control Line.



Test sample that is added to the sample well(1), with adequate amount of buffer (added to buffer well "2") migrates from the sample pad along the conjugate pad where any antigen present in the sample will bind to the antibody - conjugate. The sample then continues to migrate across the membrane until it reaches the capture zones where the antigen -antibody conjugate complex will bind to the immobilised antibody (on test line) producing a visible line on the membrane. If the respective antigen is not present in the sample, no reaction occurs in the capture zones and no test line is formed in the zone corresponding to Pf or PAN. The sample then migrates further along the strip until it reaches the control zone,

where it produces a second visible line on the membrane. This control line indicates that the sample has migrated across the membrane as intended.

MATERIALS PROVIDED

1. Each test pouch contains :
   a. One test card and sampling device (Disposable Inverted cup 5ul)
   b. Desiccant
2. Assay Buffer- In dropper bottle
3. Lancet
4. Alcohol Swab
5. Instruction Leaflet

STORAGE & STABILITY

Store the test kit between 2-30°C till the expiration date indicated on the pouch / carton. DO NOT FREEZE. Ensure that the test device is brought to room temperature before opening.

PRECAUTION & WARNING

1. Use within 10 minutes after opening pouch.
2. Do not touch result window.
3. Use only the buffer supplied along with the kit.
4. Do not mix components from different kits.
5. Use only for in-vitro diagnostic purpose.
6. Wear protective gloves while handling specimens. Clean up spills thoroughly using an appropriate disinfectant.
7. Treat all specimens, used tests and other contaminated materials as infectious, and dispose accordingly.
8. Do not use with hemolytic, lipemic or bacterially contaminated specimen.
9. Do not use with specimen containing precipitates

SAMPLE PREPARATION Specimen: Blood

- Collect the whole blood using a syringe or vacutainer into a container containing anticoagulants such as heparin, EDTA or sodium citrate by venipuncture.
- If the specimen is not used for testing immediately, they should be refrigerated at 2-8°C. For storage period longer than 5 days, freezing is recommended. Store at - 20^{0}C.

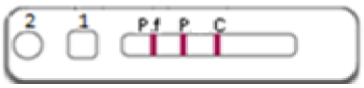
Treat the specimen as infectious and handle with standard biosafety measures.

TEST PROCEDURE

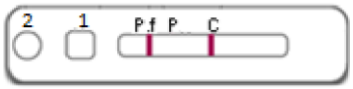
1. Take out the test card from the foil pouch and place it on a horizontal surface.
2. Add 5µl of gently swirled anti-coagulated blood or finger prick specimen in the Sample well "1" using the sampling device
3. When the sample is fully absorbed, add 3 drops of the assay buffer to the buffer well "2", by holding the plastic dropper bottle vertically.
4. Wait for 20 minutes and interpret results. The result is considered invalid after 30 minutes. All results where control band does not appear are considered invalid.

INTERPRETATION OF TEST RESULT

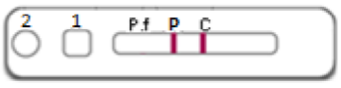
Pf & PAN Positive: Color bands at positions Pf, P and C. Malaria antigens are present in the sample.



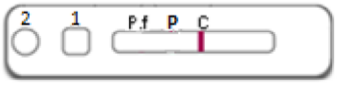
Pf Positive: Color bands at position Pf and C only. Malaria Pf antigen is present in the sample.



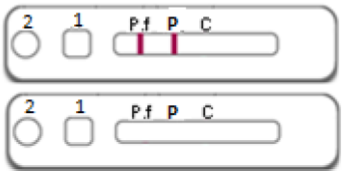
PAN Positive: Color bands at position P and C only. Malaria PAN is present in the sample.



Negative: Color bands at position "C" alone. Malaria antigens are absent in the sample.



Invalid: Color band at C does not appear



PERFORMANCE CHARACTERISTICS

Clinical Sensitivity & Specificity

Parameter	PAN/Pf
Sensitivity	**99.5%**
Specificity	**98.4 %**

Assay Cross Reactivity

No cross reactivity with other group and disease

LIMITATIONS

1. The Assay Procedure and the Interpretation of Assay Result must be followed closely when testing for the presence of Malaria Pf/PAN in the whole blood specimen from individual subjects. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
2. Sensit Malaria Pf/PAN Rapid Test is limited to the qualitative detection of antigens specific for the Malaria Pf/PAN. The intensity of the test line does not necessarily correlate to Malaria antibody titer in the specimen.
3. A negative or non-reactive result can occur if the quantity of antigen for the malaria present the specimen is below the detection limit of the assay.
4. If symptoms persist and the result from Sensit Malaria Pf/PAN is negative or non-reactive, it is recommended to re-sample the patient a few days later or test with an alternative test device.
5. The results obtained with this test should only be interpreted in conjunction with clinical findings, and the results from other laboratory tests and evaluations.
6. This test should not be used for screening of donated blood

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DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in Malaria Pf/PAN Rapid Test for single-step detection of antigen are the most common signs appearing on medical devices and their packaging. They are explained in more detail in the European Standards EN 980: 2008 and INTERNATIONAL Standard ISO 15223-1:2016

Key to symbols used			
	Manufacturer		Expiration/use by date
	Do not reuse		Date of manufacture
	Consult IFU [Instructions For Use]	LOT	Batch code
	Temperature limitation 2-30°C	IVD	In Vitro diagnostic medical device
Σ X	Contains sufficient for 'X ' kits		Do not use if package is damaged
REF	Catalogue No		Keep dry

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

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ubio Biotechnology Systems Pvt Ltd
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