Malaria P.f/P.v Antigen Rapid Test Kit

Cat. No. S005-03

In vitro Diagnostics

INTENDED USE

Sensit Malaria Pf/Pv Antigen Rapid Test Kit is a qualitative immunochromatographic assay for the simultaneous detection and differentiation of P. falciparum and P. vivax, in human blood. The Sensit Malaria P.f/Pv Antigen test is only intended for initial screening and reactive samples should be confirmed by a supplemental assay.

SUMMARY &TEST DESCRIPTION

Malaria is a mosquito-borne, acute febrile illness caused by plasmodium parasite that infects over 210 million people and kills more than 1 million people. Of over 120 species of the parasite genus Plasmodium, mainly four infects human to cause malaria: P.falciparum, P. vivax, P. ovale and P. malariae. These plasmodia infect and destroy human erythrocytes, producing chills, fever, anemia, and splenomegaly. Traditionally, Malaria is diagnosed by Giemsa Staining procedure and the species differentiation by their appearance in the infected erythrocytes. The technique is capable of accurate and reliable diagnosis, but only when performed by skilled microscopists using a defined protocol which presents major obstacles for the remote and poor areas of the world. Sensit Malaria Pf/Pv Antigen Rapid Test utilizes Anti-malaria Pf antibody to capture and detect P. falciparum HRP antigen, and Anti-malaria Pv antibody to capture and detect P.vivax LDH antigen. Thus, allowing a differential detection of P. falciparum (more severe) from other species.

TEST PRINCIPLE

Sensit Malaria Pf/Pv 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 Pv antibody, colloidal gold conjugated; b) a nitrocellulose membrane strip containing three test lines T1: Anti-malaria Pv antibody , T2: Anti-malaria Pf antibody and C: Control Line.

Test sample that is added to the sample well, with adequate amount of buffer (added to buffer well) 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 Pv. 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.

REAGENTS & MATERIAL PROVIDED

1. Each test pouch contains :
   a. One test card and inverted cup
   b. Desiccant
2. Assay Diluent- In dropper bottle
3. Lancet
4. Instruction Leaflet

STORAGE & STABILITY

1. Store the test kit between 2-30°C till the expiration date indicated on the pouch / carton.
2. DO NOT FREEZE.
3. 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

Blood:

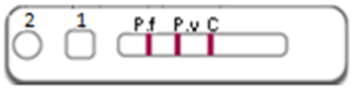
- Collect the whole blood using a syringe or vacutainer into a container containing anticoagulants such as heparin, EDTA or sodium citrate by venipuncture.
- If the specimen is not used for testing immediately, they should be refrigerated at 2-8°C. For storage period longer than 5 days, freezing is recommended. Store at - 200C.
- Treat the specimen as infectious and handle with standard biosafety measures.

TEST PROCEDURE

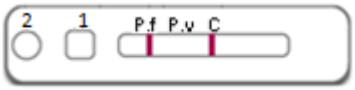
1. Take out the test card from the foil pouch and place it on a horizontal surface.
2. Add 10µl of Whole Blood to the Sample well "1"
3. When the sample is fully absorbed, add 2 drops of the diluent provided with the assay to the Buffer hole "2".
4. Wait for 20 minutes and interpret results. The result is considered invalid after 30 minutes. All results where control band does not appear are considered invalid.

INTERPRETATION OF TEST RESULT

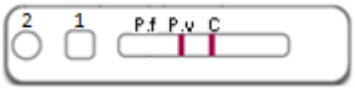
Pf & Pv Positive: Color bands at positions Pf, Pv and C



Pf Positive: Color bands at position Pf and C

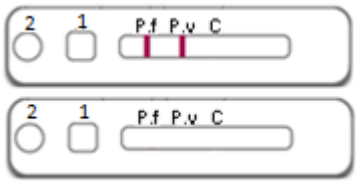


Pv Positive: Color bands at position Pv and C



Negative: Color bands at C

Invalid: Color band at C does not appear



References

1. Afzaal S, Singh M, Fatima S, et al. Rapid diagnostic tests for malaria. J Assn Physicians India. 2001; 49:261-265.
2. Detection of parasite antigens. In diagnostic procedures: Diagnostic procedures for blood specimens. Available at: http://www.dpd.cdc.gov/dpdx/HTML/DiagnosticProcedures.htm. Accessed October 5, 2002.

UBD/QA/IFU/S005-03
Rev. No: A1.1/13-10-2021

Manufactured by
ubio Biotechnology Systems Pvt Ltd
Plot # 15A,Biotechnology Zone
Kalamassery, Cochin, Kerala, India 683503
Ph:, +91-484-2970043