OXALIS
Diagnostics Pvt. Ltd.

Rapichek

Rapid Malaria Pf/Pv (Pf-HRPII/Pv-pLDH) Ag Test (Device)

For In-Vitro Diagnostic Use Only. Store at 4°C to 40°C

INTENDED USE

Rapid Malaria Pf/Pv (Pf -HRPII/Pv-pLDH) Ag Test is a lateral flow chromatographic immunoassay for the simultaneous detection and differentiation of Plasmodium falciparum (Pf -HRPII) and Plasmodium vivax (Pv-pLDH) antigen in human blood specimen. This device is intended to be used as a screening test and as an aid in the diagnosis of infection with plasmodium. The test is intended for professional use. Any reactive specimen with rapid Malaria Pf/Pv Ag test must be confirmed with alternative testing method(s) and clinical findings.

PRINCIPLE

The Rapid Malaria Pf (HRP II)/ Pv (pLDH) Antigen Test contains a membrane strip, which is pre-coated with two test lines and one control line. One monoclonal antibody (Pf - test line 1) is specific to Pf Histidine Rich Protein 2 (HRP II) of the Plasmodium falciparum species and the other line (Pv - test line 2) consists of a monoclonal antibody specific to Pv plasmodium Vivax. The control line (C) consists of Goat anti-Rabbit IgG. The conjugate pad is dispensed with HAMA blocking reagent and colloidal gold conjugated to P. falciparum specific HRP II, Pv specific pLDH antibodies and rabbit IgG. The test is designed for the differential diagnosis between malaria specific species Plasmodium falciparum and P. vivax.

After addition of the blood sample and the assay buffer to the respective wells on the test containing a test strip, the whole blood gets lysed and if the sample contains detectable levels of the Pf HRP II antigen and/or Pv pLDH antigen it reacts with the respective gold conjugated with malaria Pf specific HRP II antibodies and/or Pv pLDH specific antibodies to form a complex. The unbound colloidal gold particles along with complex move on to the nitrocellulose membrane. This complex moves further and reacts with the respective malaria Pf specific HRP II antibodies/ Pv specific Vivax antibodies test lines on the nitrocellulose membrane area to form a coloured bands (Test band/s). The unbound complex, unbound gold and the rabbit IgG conjugated colloidal gold particles move further to the goat-anti rabbit IgG coated control area to form a coloured band (C- Control line). The appearance of test lines and control line in respective area indicates the positive result. Appearance of only control line indicates a negative result. The control line acts as a procedural control. Control line should always appear if the test is performed as per the procedure and reagents are working properly.

CONTENTS OF KIT

1. Test: Nitrocellulose Membrane assembly pre-dispensed with monoclonal anti-Pf HRP II antibody, monoclonal Pv antibody, Goat anti rabbit IgG, Conjugate strip containing HAMA blocking reagent and colloidal gold conjugated monoclonal anti-Pf HRP II antibody, Pv pLDH antibody, and rabbit IgG at the respective regions.
2. Silica pouch
3. Disposable 5µl sample applicator
4. Package Insert
5. Assay Buffer

MATERIALS NEEDED BUT NOT PROVIDED

1. Calibrated micropipette capable of delivering 5µl sample accurately.
2. Timer
3. Disposable gloves

STORAGE AND SATBILITY

Store in original packing between 4°C to 40°C. Material provided are stable up to the expiration date printed on pouch/kit.

WARNINGS AND PRECAUTIONS

1. Please read the instruction carefully before performing the test.
2. For In Vitro Diagnostic use only.
3. Do not reuse the test.
4. Do not use the test after the expiration date.
5. Do not freeze, keep away from direct sunlight.
6. Do not use test if pouch is torn or damaged.
7. Use appropriate Personal Protective Equipment. Avoid direct skin contact.
8. Immediately carry out the test after removing the test device from the pouch.
9. Do not eat the Silica Gel in the package.
10. Keep away from children.
11. Do not mix or interchange the specimen sample.
12. Handle all specimen as if potentially infectious. Follow Standard Biosafety Guidelines during handling and disposal of materials to avoid the risk of infections.
13. The manufacturer and distributor of this product shall not be liable for any loses, liability, claims, costs or damages whether direct or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

SPECIMEN COLLECTION

Fresh anti-coagulated whole blood should be used as a test sample. EDTA or Heparin or Oxalate or Tri-sodium Citrate can be used as suitable anticoagulants. The specimen should be collected in a clean glass or plastic container. If immediate testing is not possible then store the specimen at 2°C to 8°C for up to three days before testing. Clotted or contaminated blood samples should not be used for performing the test. Fresh blood from finger prick/ puncture may also be used as a test specimen.

TEST PROCEDURE

1. Bring the kit components to room temperature before testing accurately.
2. Open the pouch and remove the test, sample applicator and silica gel pouch. Check the color of the silica gel. It should be blue, if it has turned colorless or pink, discard the test and use another test. Once opened, the test must be used immediately.
3. Label the test with patient's identity.
4. Tighten the vial cap of the assay buffer provided with the kit in the clockwise direction to pierce the dropper bottle nozzle.
5. Evenly mix the anti-coagulated blood sample by gentle swirling. Dip the sample loop into the sample. Ensuring that a loop full of blood is retrieved, blot the collected blood in the sample port 'S'. (This delivers approximately 5µl of the whole blood specimen).

OR

In case finger prick blood is being used, touch the sample loop to the blood on the finger prick. Ensuring that a loop full of blood is retrieved, immediately blot the specimen in the sample port 'S'. (Care should be taken that the blood sample has not clotted and the transfer to the sample port 'S' immediate).

NOTE: Ensure that the blood from the sample loop has been completely taken up at the sample port 'S'.

OR

Alternatively, 5µl of the anti-coagulated or finger prick specimen may be delivered in the sample port 'S' using a micro pipette.

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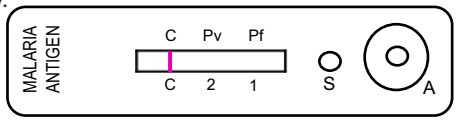
6. Immediately dispense three drops of assay buffer in to buffer port 'A', by holding the plastic dropper bottle vertically.

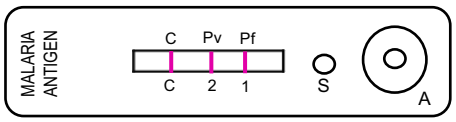
7. Read the results at the end of 20 minutes. Do not interpret the test results beyond 30 minutes.

INTERPRETATION OF RESULTS

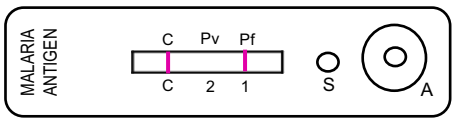
NEGATIVE for Malaria: If coloured band appears at the control region 'C' only.



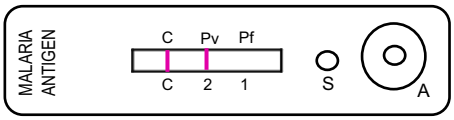
POSITIVE for P. falciparum and P.vivax mixed infection: In addition to the control band, two pink-purple bands appear at regions 'Pf' and 'Pv' in the test window.



POSITIVE for P. falciparum: In addition to the control band, one pink-purple band appears only at region 'Pf' in the test window.

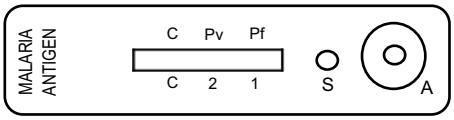


POSITIVE for P. vivax: In addition to the control band, one pink-purple band appears only at region 'Pv' in the test window.

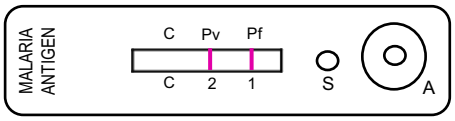


INVALID: The test should be considered invalid if,

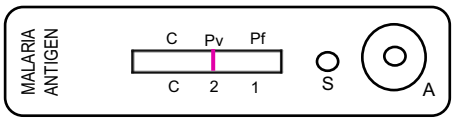
A) No line appears at 'C', 'Pf' and 'Pv' regions.



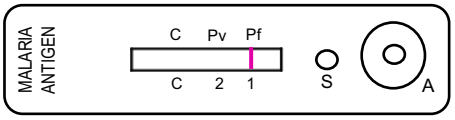
B) No line appears at 'C' region and line appear at 'Pf' and 'Pv' region.



C) No line appears at 'C' and 'Pf' region and line appear at 'Pv' region.



D) No line appears at 'C' and 'Pv' region and line appear at 'Pf' region.



PERFORMANCE CHARACTERISTICS

Internal Evaluation:

In an in-house study, total 225 samples were evaluated for sensitivity and specificity. We found the relative sensitivity was 100 % (i.e. 115/115) and the relative specificity was 100 %(i.e. 110/110). The results are summarized in the following table:

Sample	Total Number of samples tested	Rapid Malaria Pf (HRP II)/ Pv (pLDH)Antigen Test		Sensitivity (%)	Specificity (%)
		Positive	Negative		
Malaria Pf Positive Whole Blood Samples	55	55	0	100	-
Malaria Pv Positive Whole Blood Samples	60	60	0	100	-
Malaria Negative Whole Blood Samples	110	0	110	-	100

Cross reactivity was studied using RF positive samples and no cross reactivity was observed.

LIMITATIONS

1. As with all diagnostic tests, the test result must always be correlated with clinical findings.

2. The results of test are to be interpreted within the epidemiological, clinical and therapeutic context. When it seems indicated, the parasitological techniques of reference should be considered (microscopic examination of the thick smear and thin blood films).

3. Any modification to the above procedure and / or use of other reagents will invalidate the test procedure.

4. The test is limited to the detection of antigen to Malaria Plasmodium sp. Although the test is very accurate in detecting pLDH and HRP II, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

REFERENCES

1. David L. Vander Jagt, Lucy A. Hunsaker and John E. Heidrich: Partial Purification and Characterization of Lactate Dehydrogenase from Plasmodium falciparum. Molecular and Biochemical Parasitology, 4 (1981) 255-264
2. Quintana M., et. al.,(1998) Malaria diagnosis by dipstick assay in a Honduran Population with coendemic Plasmodium falciparum and Plasmodium vivax. Am. J. Trop. Med. Hyg. 59(6) 868-871
3. Hunte-Cooke A., et. al., (1999) Comparison of a Parasite Lactate Dehydrogenase-based Immunochromatographic Antigen Detection assay (OptiMAL®) with Microscopy for the Detection of Malaria Parasites in Human Blood Samples. Am J.Trop Med 60(2). 173-176.
4. John, S. M., et. al.,(1998) Evaluation of OptiMAL , a dipstick test for the diagnosis of malaria. Ann. Trop. Med. Parasitol., 92, 621-622.

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