EnCore Biomedicals

EnSure RAPID MALARIA PV/PF ANTIGEN TEST

Rapid Diagnostics Test for Malaria PV/PF

Store at 2°C to 30°C

INTENDED USE

Rapid Malaria Pv/Pf (Pv-pLDH /Pf -HRPII) Ag Test is a lateral Flow chromatographic immunoassay for the simultaneous detection and differentiation of Plasmodium vivax (Pv-pLDH) and Plasmodium falciparum (Pf -HRPII) 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 Pv/Pf Ag test must be confirmed with alternative testing method(s) and clinical findings.

PRINCIPLE OF THE ASSAY

The Rapid Malaria Pv (pLDH)/ Pf (HRP2) Antigen Test contains a membrane strip, which is pre-coated with two test lines and one control line. One (PV- test line 2) monoclonal antibody and the other line (Pf - test line 1) consists of a monoclonal antibody. The control line (C) consists of Goat anti-Rabbit IgG. After addition of the blood sample and the assay buffer to the respective ports on the test containing a test strip, the whole blood gets lysed and if the sample contains detectable levels of the Pv pLDH and Pf HRP2 antigen it reacts with the respective gold conjugated with malaria Pv pLDH specific antibodies and Pf specific HRP2 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 PV specific pLDH antibodies test lines and Pf specific HRP2 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.

PACKAGE CONTAINS

1. Each pouch contents: Test Cassettes, Sample dropper, Desiccant.
2. 1 Instruction for use per box
3. 1 Assay buffer bottle per box

MATERIALS REQUIRED BUT NOT PROVIDED

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

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 provided 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 this 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

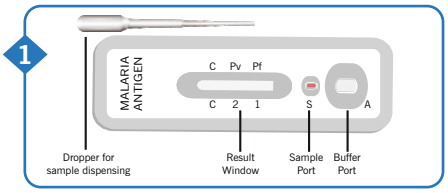
1. Bring the kit components to room temperature before testing.
2. Open the pouch and remove the test, dropper and silica gel pouch. Check the color of the silica gel. It should be blue, if it has turned colorless or pink, discard the test and use another test. Once opened, the test must be used immediately.
3. Label the test with patient's identity.
4. Add 1 drop of whole blood sample approx. 5 µl into the sample port.

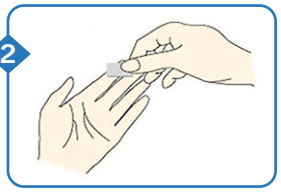
OR

In case finger is being used, touch the sample dropper to the blood on the finger prick. Ensuring that a dropper 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 is immediate).

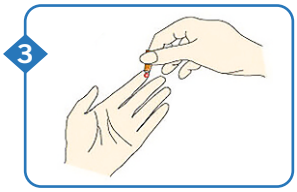
NOTE: Ensure that the blood from the sample dropper has been completely taken up at the sample port 'S'.

5. Tighten the vial cap of the assay buffer provided with the kit in the clockwise direction to pierce the dropper bottle nozzle.
6. Immediately dispense two drops of assay buffer in to buffer port 'A', by holding the plastic dropper bottle vertically. Read the results at the end of 15 minutes.

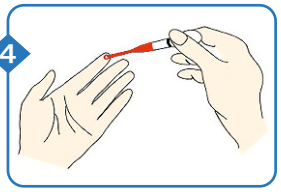




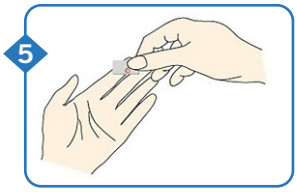
Clean finger to be pricked with an alcohol swab Allow to dry.



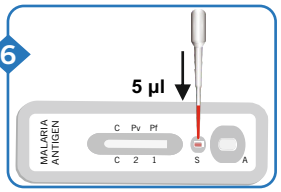
Take a lancet & prick the finger with the pointed end of the lancet



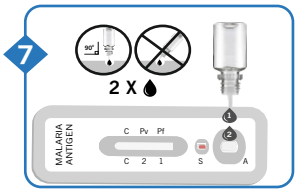
The Sample is collected with a disposable needle and the blood flows out naturally



After collection the puncture site was pressed with an alcohol cotton pad.



Add 5 µl of drawn blood in to small round port (S) touching the pad



Add 2 drops of assay buffer into big round port (A) touching the pad

Do not interpret the test results beyond 30 minutes

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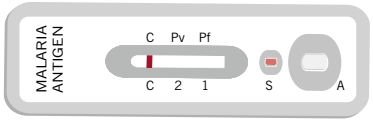
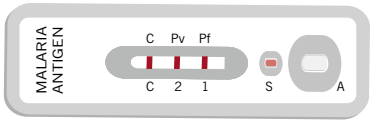
INTERPRETATION OF RESULTS

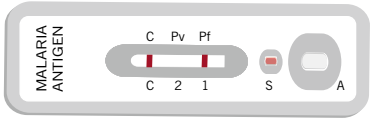
NEGATIVE for Malaria: If coloured band appears at the control region 'C' only.



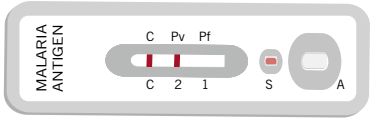
POSITIVE for P. falciparum and P. vivax mixed infection: In addition to the control band, two pink-purple bands appear at regions 'Pf' and 'Pv' in the test window.



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

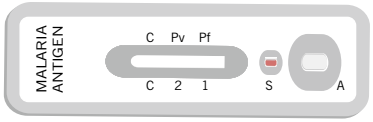


POSITIVE for P. vivax: In addition to the control band, one pink-purple band appears only at region 'Pv' in the test window.

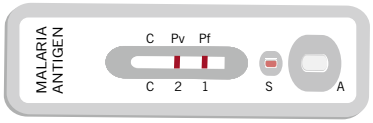


INVALID: The test should be considered invalid if,

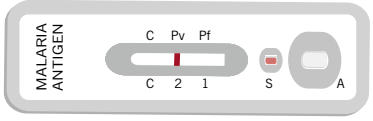
A) No line appears at 'C', 'Pf' and 'Pv' regions.



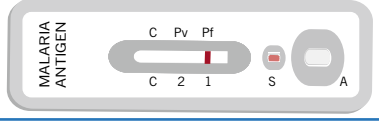
B) No line appears at 'C' region and line appear at 'Pf' and 'Pv' region



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 2) / Pv (pLDH) Antigen Test		Sensitivity (%)	Specificity (%)
		Positive	Negative		
P.falciparum Positive	55	55	0	100	-
Pv Positive	60	60	0	100	-
Malaria Negative	110	0	110	-	100

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-2, 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.
5. In case of (Pv+Pf) mixed infections, detects P. vivax as low as 100 parasite/μl even in presence of high P. falciparum densities of ~ 1,00,000 parasite/μl. In suspected cases of P. falciparum densities > 1,00,000 parasite/μl, confirm the results with microscopy.
6. P. falciparum and P. vivax malaria. However, a negative test result does not rule out the possibility of infection with P.ovale and P. malariae.
7. In P. falciparum malaria infection, Pf. HRP-2 is not secreted in gametogony stage. Hence in “Carriers”, the 'Pf' band may be absent.
8. Since Pf. HRP-2 persists for upto a fortnight even after successful therapy, a positive test result does not indicate a failed therapeutic response. If the reaction of the test remains positive with the same intensity after 5-10 days, post treatment, the possibility of a resistant strain of malaria has to be considered.

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.

SYMBOL KEY

IVD	In Vitro Diagnostic Use	2°C 30°C	Temperature limitation
	Manufacturer		Single Use only
	Manufacturing Date	Σ	Number of tests in the pack
	Expiry Date		Do not use if pouch or kit damaged
LOT	Lot Number		Read package insert before use

Manufacturer By

ENCORE BIOMEDICALS PVT. LTD.

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