Malaria PAN Ag

Rapid Malaria PAN (pLDH) Antigen Test – Device/Cassette

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

1. INTENDED USE

"Rapid Malaria PAN (pLDH) Antigen Test – Device/Cassette" is a rapid, in vitro, qualitative lateral flow immunoassay for the detection of PAN malaria specific pLDH antigen from human whole blood samples.

2. PRINCIPLE

The Rapid Malaria PAN (pLDH) Antigen Test contains a membrane strip, which is pre-coated with one test line and one control line. Test line consists of a monoclonal antibody specific to PAN plasmodium lactate dehydrogenase (pLDH). The control line (C) consists of Goat anti-Rabbit IgG. The conjugate pad is dispensed with HAMA blocking reagent and colloidal gold conjugated to PAN specific pLDH antibodies and rabbit IgG. The test is designed for the diagnosis of PAN specific species (P. vivax, falciparum, malariae and ovale).

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 PAN (pLDH) antigen it reacts with the gold conjugated with malaria PAN (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 malaria PAN (pLDH) specific antibodies test line on the nitrocellulose membrane area to form a colored band (Test band). 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 colored band (C- Control line). The appearance of test line 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.

3. MATERIAL PROVIDED

1. Test Device
2. Desiccant pouch
3. Disposable 5µl sample applicator
4. Package Insert
5. Assay Buffer

5. OPTIONAL MATERIAL REQUIRED

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

6. PRECAUTIONS/KIT STORAGE AND STABILITY

1. Please read all the information in this package insert before performing the test. Pay particular attention to the position of the Control and Test lines.
2. Do not use after the expiration date printed on the foil pouch.
3. Store in the sealed pouch in a dry place in between temperature 4°C to 40°C. Do not freeze.
4. Do not use if pouch is torn or damaged.
5. Do not open the foil pouch until you are ready to start the test.
6. Keep out of the reach of children.

7. WARNINGS

1. Do not reuse the test.
2. Follow the instruction to get accurate results.
3. Use appropriate personal protective equipment.
4. Dispose off hygienically as per local regulatory requirements.
5. Do not touch the membrane.
6. Treat blood samples and used tests as potentially infectious. Avoid contact with skin.
7. For in vitro diagnostic use. Not to be taken internally.
8. Do not eat the desiccant in the package.
9. Do not mix the specimen sample or interchange the different specimen.
10. 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.

8. 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.

9. TEST PROCEDURE

1. Bring the kit components to room temperature before testing.
2. Open the pouch and retrieve the test and desiccant pouch. Check the color of the desiccant. 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 blood so collected 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 is immediate).

OR

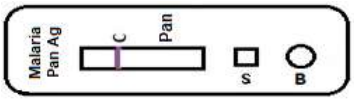
Alternatively, 5µl of the anti-coagulated or finger prick specimen may be delivered in the sample port 'S' using a micro pipette.

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

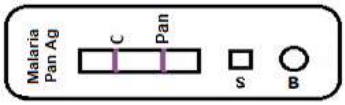
6. Immediately dispense 3 drops (Approx. 90 µl) of assay buffer into buffer port 'B', by holding the plastic dropper bottle vertically.
7. Read the results at the end of 20 minutes. Do not read the result after 30 minutes.

10. INTERPRETATION OF RESULTS

Negative for Malaria PAN: If colored band appears at the control region 'C' only.

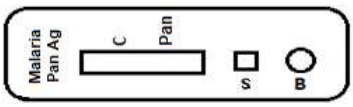


Positive for Malaria (P. vivax/malariae/ovale/falciparum Or Mixed infection): In addition to the control band, Colored band appears at test region 'Pan'

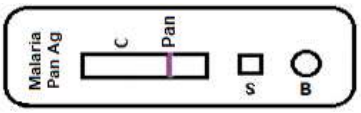


INVALID: The test should be considered invalid if,

A) No line appears at 'C' and 'Pan' regions.



B) No line appears at 'C' region and line appear only at 'Pan' region.



NOTE: The intensity of the color in the test line region (T) will vary depending on the levels of the PAN (pLDH) Antigen in the specimen. However, neither the quantitative value nor the rate of increase in Antigen in the specimen can be determined by this qualitative test. Depending on the levels of Antigen in the specimen, positive results may appear as early as five minutes. Negative results must be confirmed only at the end of 20 minutes.

11. 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. Interference due to presence of heterophile antibodies in patient's sample can lead to erroneous analyte detection in immunoassay, has been reported in various studies. uses HETEROPHILIC BLOCKING REAGENT (HBR) to inhibit majority of these interferences.
5. In case of mixed infection (P. falciparum with other malarial species), 'PAN' malaria band will be positive. Hence, differentiation of infection due to P. vivax, P. ovale or P. Malariae cannot be done.
6. While monitoring therapy, using the 'PAN' band, 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.

12. REFERENCES

1. Howard, R.J., et al., 1986: Secretion of a Malarial Histidine-rich Protein (Pf. HRPII) from Plasmodium falciparum-infected Erythrocytes.J. Cell Biol., 103, 1269-1277

2. Rock, E.P., et al., 1987: Comparative Analysis of the Plasmodium falciparum Histidine-Rich Proteins HRP-I, HRP-II and HRP-III in Malaria Parasites of Diverse Origin. Parasitol., 95, 209-227.

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

	In Vitro Diagnostic Use
	Manufacturer
	Manufacturing Date
	Expiry Date
	Lot Number
	Store at 4°C to 40°C
	Single Use
	Number of tests in the pack
	Do not use if pouch or kit damaged
	This side Up
	Read package insert before use