Malaria Antigen (Pf/Pan) Detection Test (HRP-II Pf/pLDH Pan)

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EXPLANATION OF THE TEST:

Malaria Pf/Pan Ag is a chromatographic immunoassay for the rapid, qualitative differential detection of Histidine Rich Protein II (HRP-II) antigen and Plasmodium lactate dehydrogenase (pLDH) in human whole blood. This kit is intended for the discriminational detection of Malaria P.f. infection and other pan malaria (Non-P.f malaria) infections in human blood sample. This kit is for professional use and only for the initial screening test and reactive samples should be confirmed by a supplemental assay such as microscopic examination of thin blood smear.

PRINCIPLE:

Malaria Pf/Pan Ag introduces 4 different monoclonal antibodies. Among them, two antibodies are detectable for pf-HRP II and the others are for pLDH. Anti- Pf HRP II and anti-pLDH antibody were dispensed and immobilized on the test line 'pf' for anti-HRP II and test line 'pan' for anti-pLDH on nitrocellulose membrane. Colloidal gold were also conjugated another antibodies for HRP II and pLDH. This rapid diagnostic system can be achievable to differentially diagnose P.falciparum and other species of malaria. Malaria antigens, HRP II (Histidine Rich Protein II) and LDH (lactate dehydrogenase) monoclonal antibody-coupled gold conjugate followed by reaction with anti-HRP II or anti-LDH monoclonal antibody in the test lines. When the blood sample is infected with malaria, a visible line appears in the test region on the membrane.

PRESENTATION:

Malaria Test Device
Test procedure & user information
Assay buffer
Sample Dropper (5 µl) (Inside the test device Pouch)
Sterile Lancet
Alcohol Pad

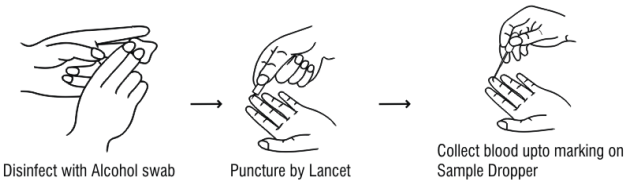
PRECAUTIONS

1. The device is sensitive to humidity as well as to heat. So, it's very important to take off the device from the sealed pouch when used.
2. Do not use the kit after the expiration date.
3. For in vitro diagnostics use only.
4. Dispose all the samples and kits properly after test, in accordance with GLP.
5. Do not pipette reagent or blood by mouth.

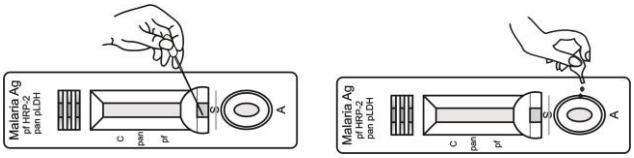
SPECIMEN COLLECTION AND STORAGE

1. The test should be performed with freshly collected human blood from the fingertip or by vein puncture using sample tube containing anticoagulant.
2. For the short term storage, please keep the specimen at 2-8ºC, for the long term storage; please keep the sample below - 20ºC.

TEST PROCEDURE:



Note: - The test device should be use immediately (within 2 minutes) after removal from the pouch.

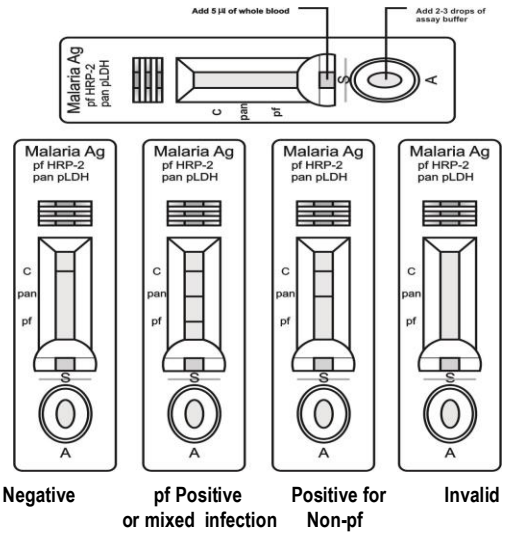


1. Clean the fingertip with the alcohol swab and let it dry completely. Prick the fingertip with a single use lancet.
2. Collect 5 µl of blood using the capillary dropper (upto indicated marking).
3. Load the 5 µl of blood into the sample well "S" of the test device.
4. Add 2-3 drops (100 µl) of assay buffer (Diluent) into the assay buffer well, "A" of the test device.
   Note: - After 5 minutes of adding specimen and buffer, you may add one more drop of assay buffer for better background clearance.
5. Immediately start the stop watch and read the results at the end of 20 minutes.
6. Refer to the following pictures for analysis of the test result.

IMPORTANT NOTE:

Results should not be read beyond 30 minutes. Reading too late can give false results.

INTERPRETATION OF RESULT



A. NEGATIVE RESULT:

Only the control band is visible. Negative result indicates that there is no malaria infection in the sample.

B. POSITIVE RESULT:

Along with the control band, if the pf and pan band appear together, the blood sample is infected with P.falciparum or mixed infection. If only the pan band appears, the blood sample is infected by P. vivax (in usual) or P.malariae / P.ovale (in rare).

C. INVALID RESULT:

If control band does not appear, the test is may be invalid. In this case, please repeat the test following the test procedure exactly.

STORAGE AND EXPIRATION

1. Malaria Pf/Pan Ag test kit should be store at between 4- 30ºC.
2. Expiration date of this kit is 24 months after its manufacture date.

PERFORMANCE CHARACTERISTICS

In an in-house study, a panel of 250 samples whose results were earlier confirmed with microscopy were tested with Malaria (Pf/Pan) Ag card. The results obtained are as follows:

Sample	Total No. of samples tested	Malaria (pf/pan) Ag test		Sensitivity (%)	Specificity (%)
		Positive	Negative		
P. falciparum positive	18	18	0	100	-
P. vivax positive	27	27	0	100	-
Malaria Negative	205	0	205	-	100

The sensitivity of Malaria antigen (pf/pan) test is compared to microscopic examination with more than 100 parasites per µl of blood.

LIMITATIONS OF THE TEST

1. Malaria Ag test is designed for primary screening test of malaria infection.
2. This kit can provide fast and easy way to get a result, but do not completely exclude the possibility of false positive or false negative result caused by various factors. So, refer to the result of this kit, please make a final decision with clinical manifestation, other test results, and doctor's view, collectively.

REFERENCES

1. World Health Organization-Geneva (2000) New perspectives malaria diagnosis.
2. Perlmann, P. and Troye-Blomberg, M.2002. Malaria parasites and disease. Malaria Immunology.
3. Malcolm, J.G.,et al, 2002.Genome sequence of the human malaria parasite Plasmodium falciparum. Nature.419:498-511
4. Warhurst,D.C., and J.E. Williams.1996. Laboratory diagnosis of malaria. J.Clin. Patol.49:533-538.

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