

# Malaria Pf/Pan Antigen Detection Test (pLDH Pf/pLDH Pan)

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## EXPLANATION OF THE TEST

The Malaria Pf/Pan test kit is a chromatographic immunoassay kit for rapid qualitative determination of Malaria infection in blood sample. Malarial antigens, LDH (Lactate dehydrogenase), in blood sample are allowed to react with the Anti-LDH monoclonal antibody-coupled gold conjugate followed by reaction with 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. The Malaria Pf/Pan Ag test can also discriminate between *P. falciparum* and *P. vivax* (Pan).

Malaria Pf/Pan Ag test can detect all 4 kinds of malaria, including *P.falciparum*, *P.vivax*, *P.malariae* and *P.ovale*.

## PRESENTATION:

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

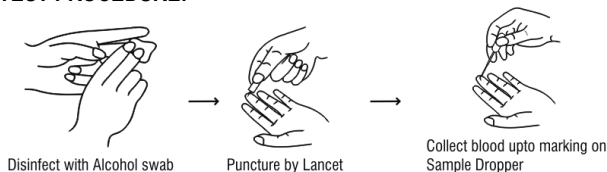
## PRECAUTIONS

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 it use.
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.

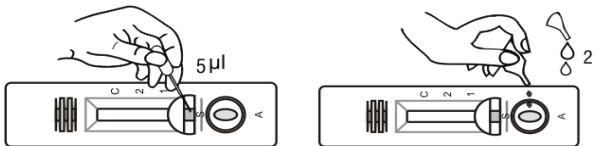
## SPECIMEN COLLECTION AND STORAGE

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

## 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.

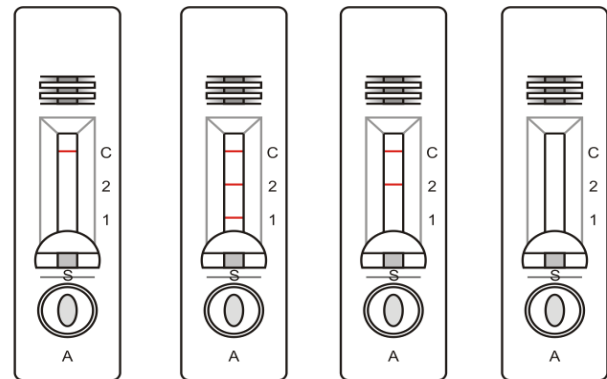
**Note: - After 5 minutes of adding specimen and buffer, you may add one more drop of assay buffer for better background clearance.**

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 RESULTS



Band on 'C'  
Area Negative

Band on 'C',  
'1', & '2' Area  
Positive for P.f.  
or mixed infection

Band on 'C' &  
2 Area Positive  
for non P.f.

No Band on  
'C' Area  
INVALID

## NEGATIVE:

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

## POSITIVE:

Along with the control band, if the T1+T2 band appear together, the blood sample is infected with *P.falciparum* or mixed infection. If only the T2 band appears, the blood sample is infected by *P. vivax* (in usual) or *P.malariae* / *P.ovale* (in rare).

## INVALID:

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- 30°C.
2. Expiration date of this kit is 24 months after its manufacture date.

## LIMITATIONS OF THE TEST

Detection limit of this kit is 100 parasites/µl of blood. Malaria Pf/Pan test is designed for primary screening test of malaria infection. 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.

