Malaria Pf/Pv Antigen

Antigen Detection Card Test

Whole Blood

INTENDED USED:

Malaria Pf/Pv Antigen detection Card Test is intended to be used for the detection of Malarial Antigens, HRP2 for P. falciparum and pLDHs for P. vivax.

PRINCIPLE OF THE TEST:

Malaria Pf/Pv Antigen is a chromatographic immunoassay kit for rapid, qualitative detection of malaria infection using whole blood specimen. Malarial antigens, HRP-II (histidine-rich protein II) and pLDH (Plasmodium lactate dehydrogenase) in the blood sample are allowed to react with the anti-HRPII and anti-pLDH monoclonal antibody coupled gold conjugate followed by reaction with anti-HRP-II antibody (Pf, test line-Pf) and/or anti-pLDH antibody (Pv, test line-Pv) in the test lines regions. When the blood sample is infected with malaria, a visible line appears in the test region on the membrane. Malaria Pf/Pv Antigen can also discriminate between P. falciparum and P. vivax.

MATERIALS PROVIDED:

Malaria Pf/Pv Antigen kit contains the following items:

1. Malaria Pf/Pv Antigen device individually foil-pouched with a desiccant and plastic loop.
2. Assay Buffer
3. Product Insert

MATERIALS REQUIRED BUT NOT PROVIDED:

1. Specimen collection container/tube.
2. Timer

PRECAUTIONS:

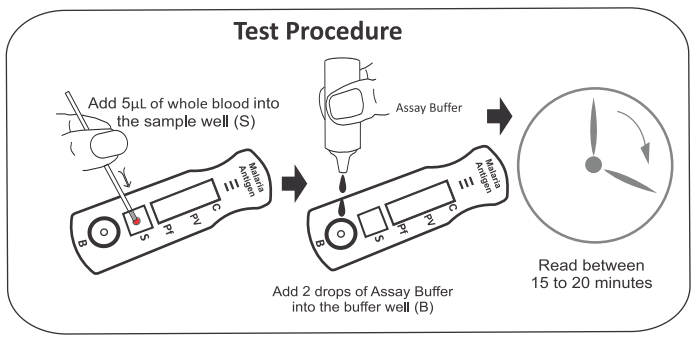
1. For *in - vitro* diagnostic use only. **IVD**
2. Wear protective gloves while handling the kit components and test specimens.
3. Patient specimens and inactivated Positive Control may contain infectious agents and should be handled and disposed off as potential biohazards.
4. Do not use kit components beyond expiry date.
5. Dispose all used materials in an appropriate container. Treat as potential biohazard.

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 anti-coagulant.
2. Collect the whole blood into the tube containig anticoagulants such as heparin, citrate, or EDTA.
3. For the short term storage, please keep the specimen at 2-8^{0}C.

TEST PROCEDURE:

1. Take out the device from the pouch and mark the patient's ID on device. Perform the test immediately after removing the device from the foil pouch
2. Clean the fingertip with the alcohol swab (not provided) and dry completely. Prick the fingertip with a single use lancet (optional). **[Caution: Do not re-use the lancet!!]**
3. Use the loop provided to load 5µL blood sample into the sample well (S) of the device.
4. Hold the dropper bottle vercically and add 2 drops of Assay Buffer into the buffer well (B) of the test device.
5. After 15 to 20 minutes, interpret the results.
6. Do not read the results after 30 minutes.



INTERPRETATION OF THE RESULTS:

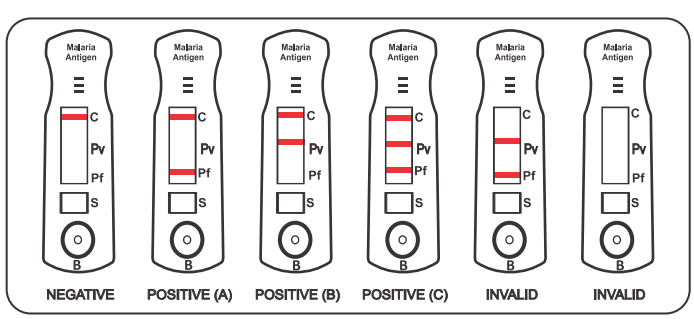
NEGATIVE: If only the control line (C) is visible. It indicates that there are no malaria antigen detectable in the sample.

POSITIVE: A) If along with the control line (C), the band for Pf is also visible. It indicates that the sample contains detectable levels of Plasmodium falciparum antigen.

POSITIVE: B) If along with the control line (C), the band for Pv is also visible. It indicates that the sample contains detectable levels of Plasmodium vivax antigen.

POSITIVE: C) If along with the control line (C), both the bands for Pf and Pv are also visible. It indicates that the sample contains detectable levels of Pf and Pv antigen.

INVALID: If the control line (C) does not appear. In this case, the test should be repeated following the exact test procedure.



STORAGE & EXPIRATION:

1. Malaria Pf/Pv Antigen kit should be stored between 4 to 30^0C.
2. Expiry date of this kit is as mentioned on the label.

QUALITY CONTROL:

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST:

Malaria Pf/Pv Antigen detection Card Test is designed for primary screening of malaria infection. This kit can provide fast and easy way to get a result, but does not completely exclude the possibility of false positive or false negative results caused by various factors. Result obtained should be correlated clinically.

PERFORMANCE CHARACTERISTICS:

Relative Sensitivity: 98.6%

Relative Specificity: 97.8%

REFERENCES:

1. World Health Organization-Geneva (2017) 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. 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.

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