Malaria Pf/PAN Antigen

Antigen Detection Card Test

Whole Blood

INTENDED USED:

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

PRINCIPLE OF THE TEST:

Malaria Pf (HRP2) / PAN (pLDH) Antigen Card Test contains a membrane strip, which is pre-coated with two test lines and one control line. on one test line there is a monoclonal antibody, Pf specific to Histidine Rich Protein 2 (HRP2) of the Plasmodium falciparum species and the other line (PAN) Has a coating 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 colloidal gold conjugated to P. falciparum specific HRP2, PAN specific pLDH antibodies and rabbit IgG. The test is designed for the differential diagnosis between Plasmodium falciparum and the other PAN specific species (P. vivax, P. malariae and P. ovale).

After addition of the blood sample and the assay buffer to the respective wells on the device, the whole blood gets lysed and moves on to react with the conjugate pad antibodies (Pf specific HRP2 , PAN specific pLDH antibodies and rabbit IgG). If the sample contains detectable levels of the Pf HRP2 antigen/ PAN pLDH antigen, it reacts with the respective antibodies to form a complex. This complex moves further and reacts with the respective Malaria Pf specific HRP2 antibodies/ PAN specific pLDH antibodies coated on the nitrocellulose membrane to form coloured band/s. The appearance of test lines and control line in respective areas indicates a positive result. Appearance of only control line indicates a negative result.

MATERIALS PROVIDED:

Malaria Pf/PAN Antigen kit contains the following items:

1. Malaria Pf/PAN 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:

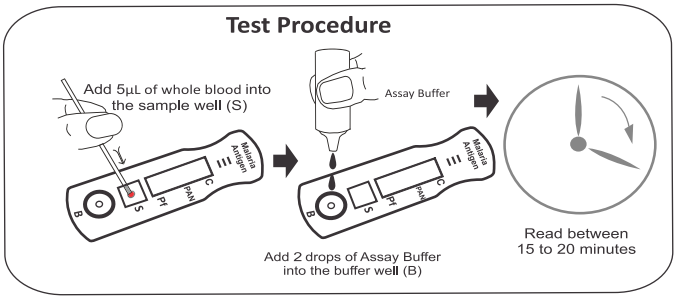
1. For in vitro diagnostic use only. IVD
2. Wear protective gloves while handling kit components and test specimens.
3. Patient specimens and inactivated Positive Control may contain infectious agents and should be handled and disposed off as potential biohazards.
4. Do not use the kit components beyond 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 containing anti-coagulants 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 to 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 reuse the lancet!!]**
3. Use the loop provided to load 5µℓ blood sample into the sample well (S) of the device.
1. Hold the dropper bottle vertically and add 2 drops of Assay Buffer into the buffer well (B) of the test device.
2. After 15 to 20 minutes, interpret the results.
3. Do not read the results after 30 minutes.



INTERPRETATION OF RESULTS:

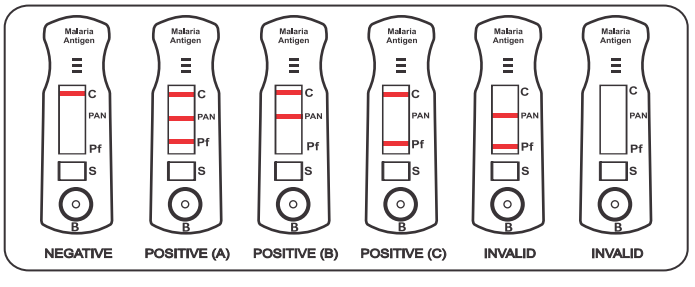
NEGATIVE for Malaria: Only one pink-purple band appears in the control window 'C'.

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

POSITIVE (B) for Other species (non falciparum): In addition to the control band, one pink-purple band appears only at region 'PAN' in the test window.

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

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/PAN Antigen kit should be stored between 4 to 30^{0}C.
2. Expiration date of this kit is as mentioned on the label.

QUALITY CONTROL:

A procedural control is included in the test. A colored line appeared 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 to be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST:

Malaria Pf/PAN Ag detection Card Test is designed for primary screening 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. Result obtained should be correlated clinically.

PERFORMANCE CHARACTERISTICS:

Relative Sensitivity: 98.4%

Relative Specificity: 97.5%

REFERENCES:

1. World Health Organization-Geneva (2000) new perspectives malaria diagnosis.
2. Perlmann, P. and Troye-Blomberg, M. (2002.) Malariaparasites and disease. Malaria Immunology.
3. Malcolm, J. G., et al, (2002) Genome sequence of the human malariaparasite Plasmodium falciparum.Nature. 419: 498-511

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