

Malaria pf (HRP II) / (PAN-LDH) Antigen Rapid Test

For detection of Malaria antigens in Whole Blood.



In-vitro diagnostic use only



Not reuse

Introduction

Malaria is a serious parasitic disease characterized by fever, chills, and anemia and is caused by a parasite that is transmitted from one human to another by the bite of infected Anopheles mosquitoes. There are four kinds of malaria that can infect humans: *Plasmodium falciparum*, *P. vivax*, *P. ovale*, and *P. malariae*. In humans, the parasites (called sporozoites) migrate to the liver where they mature and release another form, the merozoites. The disease now occurs in more than 90 countries worldwide, and it is estimated that there are over 500 million clinical cases and 2.7 million malaria-caused deaths per year. At the present, malaria is diagnosed by looking for the parasites in a drop of blood. Blood will be put onto a microscope slide and stained so that the parasites will be visible under a microscope.

The Malaria pf (HRP II) / (PAN-LDH) Antigen Detection Test Device (Whole Blood) contains a membrane strip, which is pre-coated with two monoclonal antibodies as two separate lines across a test strip. One monoclonal antibody (test line 1) is specific to the *P. falciparum* histidine rich protein-2 (Pf HRP-2) and another monoclonal antibody (test line 2) is pan to the lactate dehydrogenase of Plasmodium species (*P. falciparum*, *vivax*, *malariae*, *ovale*). Conjugate pad is dispensed with monoclonal antibodies conjugated to colloidal gold, which are specific to *P. falciparum* histidine rich protein-2 (Pf HRP-2) and pan to the lactate dehydrogenase of *Plasmodium species*.

The Malaria pf (HRP II) / (PAN-LDH) Antigen Detection Test Device (Whole Blood) is designed for the differential diagnosis between *Plasmodium falciparum* and the other *Plasmodium species*

Intended Use

For the rapid qualitative determination of Malaria *P. falciparum* specific histidine rich protein-2 (Pf HRP-2) and Malaria pan lactate dehydrogenase (PAN-LDH) in human blood as an aid in the diagnosis of Malaria infection.

Materials Included and Active Ingredients

- 1) Malaria pf/pan Ag kit contains the following items to perform the assay.
 - Malaria pf/pan Ag test device foil pouched with a desiccant
 - Assay Buffer
 - Instruction for use
- 2) Active ingredients of main components of one Malaria pf/pan Ag test strip
 - Gold Conjugates (as main component): Mouse monoclonal antibodies specific to p.f HRP-II-gold colloid ($0.20 \pm 0.036 \mu\text{g}$), Mouse monoclonal antibodies pan specific to pLDH-gold colloid ($0.06 \pm 0.012 \mu\text{g}$)
 - Test Line p.f (as main component): Mouse monoclonal antibodies specific to *P.f* HRP-II ($0.32 \pm 0.064 \mu\text{g}$); Test Line Pan: Mouse monoclonal antibodies pan specific to pLDH ($0.80 \pm 0.16 \mu\text{g}$)
- 3) Control Line (as main component): Recombinant pPM-LDH antigen ($0.64 \pm 0.13 \mu\text{g}$)

Kit Precautions and Storage Instructions

- 1) For best results, adhere to instructions provided
- 2) All specimens should be handled as potentially infectious
- 3) The test device should be stored at room temperature
- 4) The test device is sensitive to humidity as well as heat
- 5) Do not use beyond expiration date
- 6) Do not use test kit if pouch is damaged or seal is broken
- 7) Use test device immediately after removing from the pouch
- 8) The components (test device and assay diluents) in this kit have been quality control tested as a standard batch unit. Do not mix components from different lot numbers.

Warnings

- 1) For in vitro diagnostic use only. DO NOT RE-USE test device
- 2) The instructions must be followed to obtain accurate results. Anyone performing an assay with this product must be trained in its use and laboratory procedures.
- 3) Do not eat or smoke while handling specimens
- 4) Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
- 5) Avoid splashing or aerosol formation
- 6) Clean up spills thoroughly using an appropriate disinfectant
- 7) Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
- 8) Do not mix with other specimens.

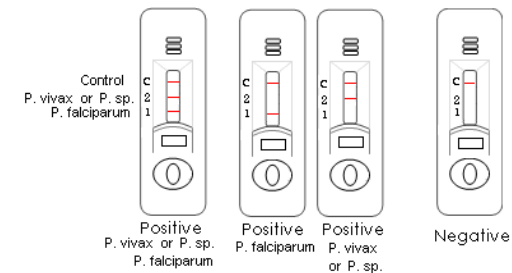
Specimen Collection, Storage and Precautions

- 1) Whole Blood (WB): Collect the whole blood by lancing devices. WB can be delivered by pipette directly to the test card.
- 2) If specimens are not immediately tested, they should be refrigerated at $2 \sim 8^{\circ}\text{C}$. For storage periods greater than three days, freezing is recommended. They should be brought to room temperature prior to use. Using the specimen after long-term storage of more than three days can cause non-specific reaction.
- 3) When stored at $2 \sim 8^{\circ}\text{C}$, the whole blood sample should be used within three days.
- 4) Anticoagulants such as heparin, EDTA and sodium citrate do not affect the test results.
- 5) Use separately disposable capillary pipettes or pipette tips for each sample in order to avoid cross-contamination of either samples which could cause erroneous results.
- 6) As known relevant interference, hemolytic samples, rheumatoid factors-contained samples and lipaemic, icteric samples can lead to impair the test results.

Test Procedure

- 1) Allow all test components and specimen to come to room temperature prior to testing
- 2) Remove the test device from the foil pouch, and place it on a flat, dry surface
- 3) With a micropipette (not provided) or a disposable dropper, add about 5 -10 μL whole blood specimen into the sample well marked "S"
- 4) Add two drops (80 μL) of assay buffer into developer well
- 5) As the test begins to work, you will see red color move across the result window in the center of the test device.
- 6) Interpret test results at 15-20 minutes. Caution: Do not read test results after 20 minutes. Reading too late can give false results.

Interpretation of Test Results (Refer to Figure)



1) *P. falciparum* Positive reaction

The presence of two color bands (c and 1) indicates a positive result for *P. falciparum*. The Pf HRP-2 present in the sample reacts with the Pf HRP-2 conjugate and move through the test strip where the Pf HRP-2 is captured by the anti- *P. falciparum* specific histidine rich protein-2 (Pf HRP-2).

2) *P. vivax* or other *Plasmodium* species Positive reaction

The presence of two color bands (c and 2) indicates a positive result for *P. vivax* or other *Plasmodium* sp. The PAN-LDH present in the sample reacts with the pan anti-PAN-LDH conjugate and move through the test strip where the PAN-LDH is captured by pan specific anti-PAN-LDH.

3) The presence of three color bands indicates a positive result for *P. falciparum* and *P. vivax*. The Pf HRP-2 present in the sample reacts with the Pf HRP-2 conjugate and move through the test strip where the Pf HRP-2 is captured by the anti- *P. falciparum* specific histidine rich protein-2 (Pf HRP-2).

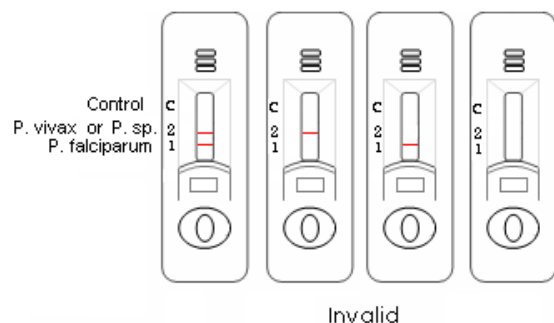
The PAN-LDH present in the sample reacts with the anti-PAN-LDH conjugate and moves through the test strip where the PAN-LDH is captured by the anti-PAN-LDH.

4) Negative reaction

The presence of only one band within the result window indicates a negative result.

5) Invalid

The test is invalid if the control line does not appear. If this occurs, the test should be repeated using a new strip



Limitations of the Test

- 1) The test procedure, precautions and interpretation of results for this test must be followed when testing.
- 2) Anti-coagulants such as heparin, EDTA, and citrate do not affect the test result.
- 3) This test kit detects *Plasmodium* HRP-2 and lactate dehydrogenase in patient whole blood and is useful as a screening procedure of malaria diagnosis.
- 4) Do not mix reagent of different lots.
- 5) The test is limited to the detection of antigen to Malaria *Plasmodium* sp. Although the test is very accurate in detecting HRP-2 and PAN-LDH, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

Suggested Readings

- 1) Cameron R. Dunn, Mark J. Banfield, John J. Barker, Christopher W. Highm, Kathleen M. Moreton, Dilek Turgut-Balik, R. Leo Brady and J. John Holbrook. The Structure of lactate dehydrogenase from *Plasmodium falciparum* reveals a new target for anti-malarial design. *Nature Structural Biology* 3(11)1996, 912-915
- 2) Howard, RJ, et al. The secretion of a Malaria Histidine-rich Protein (Pf HRP II) from *Plasmodium falciparum*-infected Erythrocytes. *J. Cell Biol.*, (1986)103, 1269-1277
- 3) Rock, EP, et al. Comparative Analysis of the *Plasmodium falciparum* Histidine-Rich Proteins HRP-I, HRP-II, and HRP-III in Malaria Parasites of Diverse Origin. *Parasitol.*, (1987) 95:209-227
- 4) Parra, ME, et al, Identification of *Plasmodium falciparum* Histidine-Rich Protein 2 in the plasma of Humans with Malaria. *J. Clin. Microbiol.*, (1991) 29:1629-1634
- 5) Rodriguez-del Valle, M., et al, Detection of Antigens and Antibodies in the Urine of Humans with *Plasmodium falciparum* Malaria. *J. Clin. Microbiol.*, (1991) 29:1236-1242

REF

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